

ANNUAL REPORT

2020



**BONESUPPORT™** is a fast growing orthobiologics company that focuses on innovative products for the treatment of bone disorders. The company develops and sells injectable bio-ceramic bone graft substitutes based on its CERAMENT® platform, which remodels to bone and has the ability to release pharmaceuticals to promote healing.

**BONESUPPORT™** markets CERAMENT®|BONE VOID FILLER (BVF), CERAMENT®|G and CERAMENT®V, and is developing pre-clinical product candidates that are designed to promote bone regrowth. BONESUPPORT's products focus on trauma, revision arthroplasty (replacement of joint prostheses), chronic osteomyelitis (bone infection) and foot and ankle surgery.

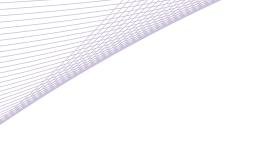
**BONESUPPORT** has its registered office in Sweden and is listed on Nasdaq Stockholm. Net sales in 2020 amounted to SEK 181 million (155) and the company had 95 (89) employees at year-end.

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CERAMENT® is a registered trademark of BONESUPPORT AB



## 2020 IN BRIEF

## **IMPORTANT EVENTS**

- In March, the Food and Drug Administration (FDA) designated CERAMENT G a "Breakthrough Device".
- In April, the company submitted a De Novo application to the FDA to obtain market approval for the company's antibiotic-releasing product CERAMENT G. In February 2021, the company received a notification from the FDA requiring additional data.
- In May, BONESUPPORT carried out a directed new share issue of SEK 378 million before issue costs.
- Michael Roth took over as General Manager & Executive Vice President Commercial Operations, North America in June. Michael Roth succeeds Patrick O'Donnell, who left the business in February.
- In June, BONESUPPORT announced that it was starting its own sales organization in the Netherlands.
- Patient recruitment for FORTIFY ended in June, after approval by the FDA.
- In November, BONESUPPORT announced that Simon Cartmell left the company's Board of Directors.

## **FINANCIAL RESULTS**

## Turnover

181

**SEKm** 

Net sales amounted to SEK 181 million (155), an increase of 16%. The North America segment increased by 47% and the EUROW segment reported a 7% decline in sales.

## Margin

89

Gross margin amounted to 89% (87). The strong growth in the U.S. is a contributing factor to the improvement in gross margin.

## **Profit/Loss**

SEKm

Operating loss amounted to SEK -99 million (-158).

## Earnings/share

-1.72

SEK

Earnings per share before and after dilution were SEK -1.72 (-3.10).

## **COVID-19 PANDEMIC**

The pandemic has had a major impact on the financial year. The healthcare system has been forced to prioritize infection and intensive care with the result that non-critical orthopedic operations were postponed. In addition, the public restrictions imposed have resulted in a lower level of activity in the population, which has led to fewer acute trauma operations.

In the longer term, the pandemic is expected to have a limited impact on the needs for BONESUPPORT's products, be it emergency or planned operations.

# Our soul...



## **MISSION**

Improving the health and quality of life for patients with bone disorders

BONESUPPORT's unique product technology has properties with the potential to revolutionize the care of patients with skeletal injuries, by enabling faster rehabilitation, limiting the number of surgical procedures and reducing the risk of severe infections. For patients, this means that they can return to a normal life more quickly.

Since its foundation, BONESUPPORT's products have been used in approximately 55,000 surgical procedures in more than 20 countries. The most common procedures are tibia, foot and ankle surgery and single-stage surgery in connection with bone infection.



## **VISION**

## To become a global orthobiologics leader

BONESUPPORT's unique technology means that over time, the company's injectable bio-ceramic bone graft substitutes remodel to natural bones and have the ability to release drugs. This enables new treatment standards in the treatment of bone diseases/skeletal injuries.

The company's ambition is to grow sales by 40 percent a year after the pandemic, including through a rapid expansion in the U.S., which is the world's largest healthcare market.



## **STRATEGY**

## The strategy is based on three pillars:

**Innovation** – BONESUPPORT has the most innovative solution for the treatment of skeletal injuries on the market. In 2020, investments in research and development amounted to SEK 58 million (69).

## Clinical and Health Economic Evidence -

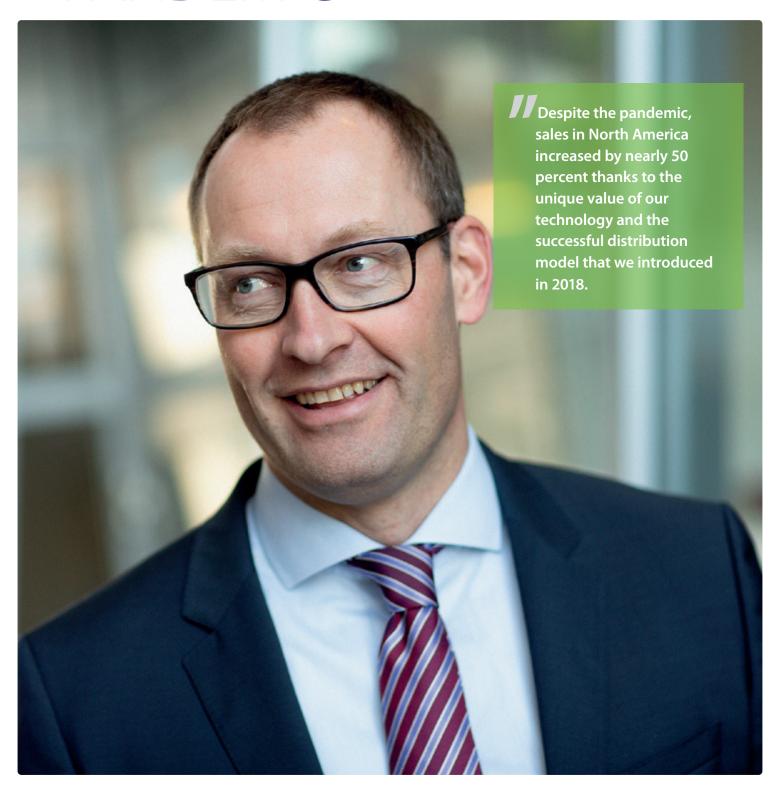
The clinical evidence for the CERAMENT platform continues to grow and now amounts to more than 160 publications. An important milestone for BONESUPPORT is CERTIFy, the largest randomized controlled trial for a synthetic bone graft substitute that shows that CERAMENT is at least as good as autograft.

## Effective commercial platform -

BONESUPPORT's commercial and medical organization provides healthcare with products, information, service and education.

.. our heart

## DOUBLE-DIGIT GROWTH DESPITE ONGOING PANDEMIC



In 2020, many important steps were taken towards our vision of becoming a globally leading company in orthobiology. The COVID-19 pandemic slowed down growth, but BONESUPPORT's underlying business developed strongly in 2020 and we reached several important milestones. We have worked diligently towards our strategy for increased market penetration of CERAMENT.

For the full year, BONESUPPORT grew 16 percent, which was nearly 30 percentage points above market growth (U.S.+EU), according to estimates from market institutes and analysts.

Despite the pandemic, sales in North America increased by nearly 50 percent thanks to the unique value of our technology and the successful distribution model that we introduced in 2018 and have been developing since then. In particular, continued geographical expansion and increased market share among established customers has driven the strong growth, which has also led to a continuously improved gross margin of close to 90 percent.

During the spring, we received a breakthrough designation for CERAMENT G for the indication osteomyelitis from the U.S. Food and Drug Administration (FDA) and shortly thereafter we submitted a De Novo application for CERAMENT G. In February 2021, the FDA announced that it wants to see additional data and clarifications, especially regarding the CERAMENT G control group. We will therefore be sending supplementary data in October 2021 and have revised our time schedule for potential market approval for the indication osteomyelitis to the first quarter of 2022.

Our plan to submit a PMA application by the end of 2021 for further indications, including trauma, remains in place. The application will be based on the results of the randomized controlled trial, FORTIFY. The trial was initiated in 2017 with the aim of evaluating the safety and efficacy of CERAMENT G in open tibia fractures, compared to current standards of care. The trial recruited the last patient in June 2020. The trial is proceeding according to plan and the results are expected to be available in the third quarter of 2021.

BONESUPPORT estimates that the U.S. market for the indication bone infection is about USD 100 million, with annual growth of 6-7 percent. The approval within the indication trauma, where there is a high risk of bacterial contamination, will further open up the market. In order to finance the commercialization of CERAMENT G in the U.S., we carried out a successful and oversubscribed rights issue during the second quarter that provided the company with SEK 378 million before issue costs.

The pandemic has had a major impact on our sales during the year. Non-critical orthopedic surgeries have been postponed and, in addition, a generally lower level of activity in society led to fewer acute trauma operations. Overall, the number of orthopedic surgeries in hospitals and clinics in both the U.S. and Europe was significantly lower in 2020 than in previous years. A concrete example from the Swedish Perioperative Register (SPOR) shows that 91,000 fewer operations were performed in Sweden in 2020 compared to 2019, which corresponds to a decrease of almost 20 percent. The operations postponed in 2020 add to existing long waiting lists for care around the world.

In the longer term, the pandemic is expected to have a limited impact on the demand for BONESUPPORT's products, be it for emergency or planned operations. However, the need for effective healthcare will be greater than ever. CERAMENT enables a single stage procedure instead of the multiple surgeries that are currently the prevailing standard. CERAMENT will thus make a unique contribution to orthopedic procedures, in terms of reducing the healthcare debt that the pandemic has contributed to increasing. CERAMENT has the potential to replace autograft and other treatment options to a large extent, which can improve the lives of patients and reduce the future costs of treating skeletal injuries

We are well on our way to establishing CERAMENT as a standard treatment for skeletal injuries in a number of key markets. We have a proven and scalable business model that has delivered great results in a number of markets. In 2020, we established our own sales team in the Netherlands. which means that we now have our own sales force in Denmark, the Netherlands, Switzerland, the UK, Sweden and Germany, as well as a network of independent distributors in the U.S.. I look forward to the investments we have made in our commercial infrastructure having the chance to deliver results in line with their full potential as the pandemic recedes. In the latter half of 2020, we started collaborations with distributors in Australia and South Africa. In Australia, CERAMENT is now used in single stage procedures at a number of university hospitals and shortly after Christmas the first CERAMENT G operation was carried out in South Africa.

In our research portfolio, we are focused on harnessing CERAMENT's unique pharmaceutical release properties by developing combination products that promote bone healing. One of the indication areas that we are studying is fractures caused by osteoporosis. These fractures are often painful, debilitating and can be life-threatening. They affect one in three women and one in five men over the age of 50 and it is a globally growing problem that is often treated systemically with Zoledronic acid. In 2019, preclinical data was published showing that the combination of Zoledronic acid and CERAMENT can increase bone volume and improve anchoring of screw implants. At the end of 2020, additional preclinical data was published showing that a combination of CERAMENT with a low dose of bone morphogenic protein-2 and Zoledronic acid can completely heal major skeletal damage. The study was published in the very reputable journal Science Advances.

The pandemic triggered a successful digital transformation, which has enabled us to meet customers, both existing and potential, in new effective ways. During the year, we conducted a number of well-attended digital seminars and webinars. In total, more than 350 surgeons participated in our digital seminars and training sessions. To some extent, the benefits of these digital initiatives have been shown in increased sales, but above all our increased digital presence has been an investment in the future.

I am proud of the organization's ability to adapt the business to the current circumstances. CERAMENT is a unique technology that will introduce a clear paradigm shift in the care of skeletal injuries. In 2021, we will ensure the existence of control data for a potential De Novo approval of CERAMENT G in the U.S. for the treatment of osteomyelitis. In addition, we look forward to strong results from the FORTIFY trial paving the way for further indications.

We believe that during early 2021 the pandemic will continue to supress our sales as well as our ability to meet surgeons in hospitals, but that we can accelerate our growth as the year progresses. In the long term, our goal remains to grow sales by 40 percent per year.

Emil Billbäck CEO

## CERAMENT

# Promoting natural healing

CERAMENT is a synthetic bone graft substitute for the treatment of bone injuries. The material has unique advantages in that it promotes bone regrowth, which means that CERAMENT is reabsorbed within six to twelve months and is replaced by the patient's own bone tissue. CERAMENT is injectable and visible on X-rays, which makes it ideal for minimally invasive surgery. CERAMENT is also available as a combination product with two different types of antibiotic, CERAMENT G (gentamicin) and CERAMENT V (vancomycin). The antibiotics are released locally for about 30 days and protect the healing bone from infection.

## WHEN BONE INJURIES OCCUR THAT DO NOT HEAL

There are a variety of situations where the natural healing of skeletal injuries is not successful. This can occur, for example, with complicated fractures (trauma), revision arthroplasty (replacement of joint prostheses), tumors or infection. This may be due to missing bone fragments or when the injury is too large for the bone to heal. If these lesions are not treated, there is a risk of severe complications. Traditionally, orthopedic surgeons have treated skeletal injuries, that do not heal themselves, using the patient's own bone tissue, transplanted from another part of the bone structure, known as autograft, or via donated bone tissue, transplanted from one person to another, known as allograft.

## TRADITIONAL TREATMENT STANDARD

Since autograft consists of the patient's own bone tissue, tolerance and healing are usually good. However, autograft requires an additional surgical procedure (most commonly at the hip bone) to harvest the bone tissue to be transplanted. The bone tissue available may also be limited in relation to the need. Each procedure uses additional surgical resources from the healthcare system, increases the risk of infection which could extend ther period of medical care. Nearly 50 percent of patients experience restrictions in daily activities for up to six months after the procedure as well as long-term pain from the donor site. There are studies1 that show that many patients can even experience pain for up to ten years after the procedure. Allograft is affected by limited supply and quality, and also poses a risk of the transmission of viral diseases.

<sup>1</sup> Long term Autograft Harvest Site Pain After Ankle and Hindfoot Arthrodesis. Judith F. Baumhauer et al.



## CERAMENT – A SYNTHETIC ALTERNATIVE WITH ESSENTIAL BENEFITS FOR THE PATIENT AND THE HEALTHCARE SYSTEM

CERAMENT is remodelled into endogenous bone, which means that the original injury is replaced by the patient's own bone within six to twelve months. In the CERTIFy trial, a randomized controlled trial of 135 patients, showed that CERAMENT is a complete alternative to the previous gold standard treatment autograft.

CERAMENT is a synthetic bone graft substitute, effectively eliminating the need for additional surgical procedures to harvest bone tissue and hence the risk of shortage of material. Studies have shown that many patients experience restrictions in daily

activities for up to six months after the procedure, as well as long-term pain from the donor site. A recent study from J Baumhauer et al showed that patients can experience severe pain for up to ten years after a surgical autografting procedure. The great advantages of CERAMENT are:

- Predictable results
- Easy to use
- Unlimited availability
- No need to take bone from donors
- Elimination of complications such as long term pain

## CERAMENT WITH ANTIBIOTICS – WHEN THE RISK OF INFECTION ASSOCIATED WITH SKELETAL INJURIES IS HIGH

Chronic bone infection, open trauma fractures, and unsuccessful bone healing are a few of the conditions that are strongly associated with the risk of (re)infection. Postoperative infection is not only associated with significant suffering for the individual, but also involves an extensive use of resources and a cost burden for society-at-large. Hoekstra et al (BE) showed that the healthcare costs for patients who suffered a deep infection were on average five times higher than for those who did not get an infection, in the case of severe tibia fractures. The combination products CERAMENT G and CERAMENT V effectively promote and protect bone healing by eluting high-dose local antibiotics at levels that eliminate bacterial growth. With CERAMENT G and CERAMENT V, a high local concentration of antibiotics is maintained, for approximately 30 days with negligible systemic influence and side effects. Treatment with CERAMENT G and CERAMENT V has shown a drastic reduction in re-infection in cases of chronic bone infection and elimination of infection incidence in open tibia fractures (see section Clinical evidence). CERAMENT G and CERAMENT V enable healthcare to perform single-stage operations in connection with injuries caused by infection or when there is a high risk of infection. This contributes to fewer days of care in hospitals and thus better healthcare economy.

As CERAMENT has been proven to be as effective as autograft in healing skeletal injuries, the need for an additional operation is eliminated, resulting in better utilization of resources concerning both surgical teams and operating theaters. A product that can both regenerate bone and at the same time elute high doses of local antibiotics over approx. 30 days has also opened up the possibility of using single stage surgery in the treatment of bone infections and open fractures.

## The benefits of CERAMENT G and CERAMENT V

- Predictable local antibiotic elution
- Possibility of treating with a surgical single stage operation
- Increased possibility of being infection-free
- Increased possibility of rapid bone healing
- Reduced risk of amputation

Indication area	Risk of infection <sup>1</sup>	Cost <sup>1</sup>		
Trauma	1-50%2	61-150 USDt		
Oncology	10-15%	20-30 USDt		
Ankle	2-20%	20 USDt		

Trauma severity accordi Anderson classification	Risk of amputation			
II	2-7%	low		
IIIA	10-25%	low-medium		
IIIB	10-50%	up to 16%		
IIIC	25-50%	up to 50%		

<sup>1</sup> E M Schwartz et al. 2018 International Consensus Meeting on Musculoskeletal Infection: Research Priorities from the General Assembly Questions, Volume 37, Issue 5 Pages: 991-1201 May 2019.

<sup>2</sup> Jahangir et al. "The use of adjuvant local antibiotic hydroxyapatite bio-compositein the management of open Gustilo Anderson type IIIB fractures. A prospective review." Journal of orthopedics vol. 16,3 278-282.



## **MARKET EXPANSION**

## Strategic progress despite the impact of the pandemic

During the year, we strengthened our position in North America at the same time as establishing our own sales organization in the Benelux region and revitalizing our distributor markets.

The COVID-19 pandemic has had a significant impact on sales growth in 2020, which nevertheless amounted to 16 percent, mainly driven by an early autumn recovery from the pandemic in North America, with a less prominent recovery in EUROW.

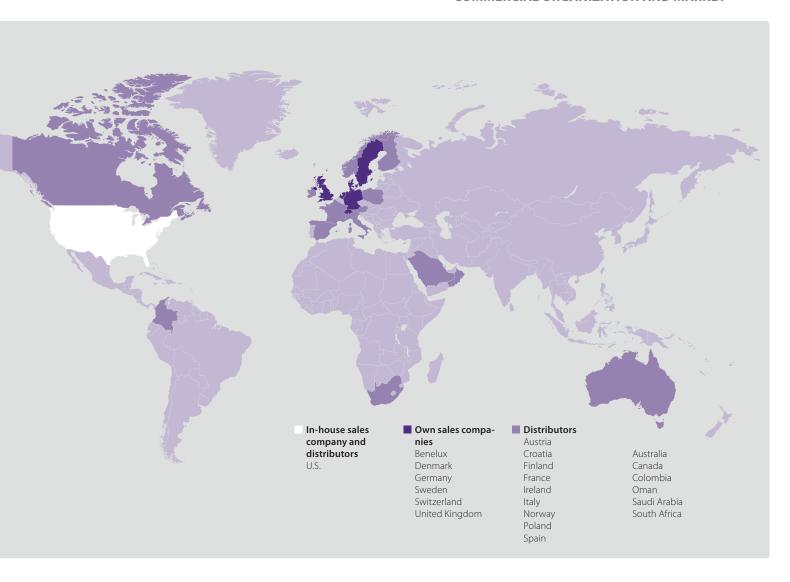
## Successful customer expansion in North America

The successful customer expansion that has been going on in the U.S. since we shifted our distribution strategy almost two years ago continues to deliver good results. The increasing market penetration can be attributed, among other things, to the larger Group Purchasing Organisation (GPO) contracts signed in 2019, which enabled the introduction of CERAMENT BVF in a number of hospitals and clinics that had not previously been approached and informed of the benefits of CERAMENT. Sales to these new customers have compensated for the temporary decline in sales among established customers caused by the reprioritization of non-critical surgery during the pandemic.

With a broad and loyal customer base in the U.S., we have built a strong foundation for continued geographical expansion and increased market share.

At the end of the year, our commercial organization in the U.S. had 22 employees and 40 contracted distributors. BONESUPPORT reports net sales to customers on which distributors receive a commission.





## Continued market expansion in EUROW despite the pandemic

Despite the impact of the COVID-19 pandemic on the opportunities for market processing and sales, we have continued to strengthen our market presence during the year, partly through the fact that we have started our own sales organization in the Benelux region and partly through the revitalization of our distributor markets. Today, we have our own sales organizations in the Benelux region, Denmark, Switzerland, the UK, Sweden and Germany. Other markets are processed through distributors with a focus on orthopedics and we have added Australia and South Africa to those markets during the year.

The impact of the pandemic has accelerated the digital transition. The positive experience of CERAMENT among our established users, including university hospitals, has been spread to a larger target group through webinars. Our digital training and meetings have been very well attended and received very good reviews. We have ensured accreditation of training sessions, which has given added value to those doctors who have to achieve a certain number of training credits each year.

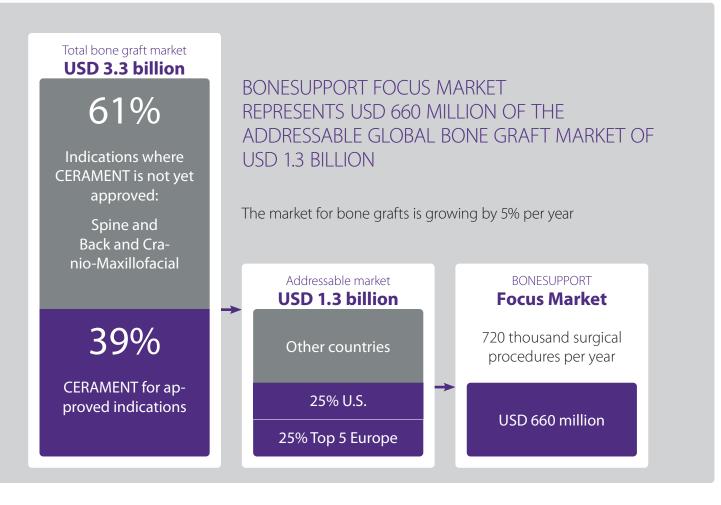


## THE GLOBAL MARKET FOR BONE GRAFT AMOUNTS TO USD 3.3 BILLION

Orthopedic diseases and injuries are the second most common cause of physical impairment or disability. The demographic structure is a driving factor for an increasing need for treatment of the diseases of the organs of movement: an increasing number of elderly people leads to higher incidence of osteoporosis and osteoarthritis, as well as a greater desire to remain active for longer and increased sports activity.

Bone has the ability to heal completely, without leaving any traces of injury. However, bone damage that leads to voids and bone defects may occur when the damage to the bone is too significant to heal

spontaneously or when the natural healing process is inhibited, for instance in the event of infection. The most common underlying causes of voids in bone and bone defects are complicated fractures (trauma), revision arthroplasty (replacement of joint prostheses), bone infection or benign bone tumors. The obvious benefits of synthetic bone grafts mean that their use will grow steadily, at the expense of autograft and allograft. BONESUPPORT's CERAMENT products are synthetic bone grafts and are unique in their ability to remodel to bone within 6-12 months and, in the case of CERAMENT G and CERAMENT V, to release antibiotics to protect the bone healing process from infection.



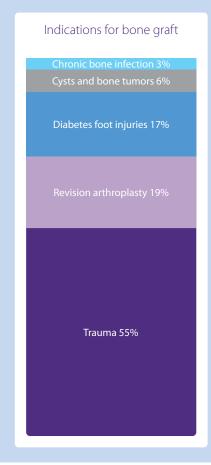
## INDICATIONS AND TREATMENT OPTIONS

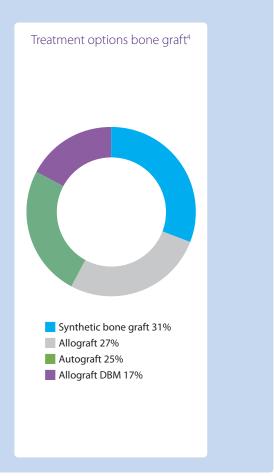
## **Previous standard treatment** (organic grafts/transplantation):

47% of patients' everyday life is adversely affected<sup>1</sup> up to 6 months after treatment with autograft due to pain at the donation site. 39% of patients experience long term pain from the donor site.

Allograft fails on between 25-50% of occasions 2,3 requiring additional treatment stages.

- 1. Lementovski et al. 'Acute and chronic complications of intracortical iliac crest bone grafting versus the traditional corticocancellous technique for spinal fusion surgery.' Orthopedics (2010);33.
- 2. http://www,surgeryencyclopedia.com/A-Ce/Bone-Grafting,html
- 3. Zheng et al, Mechanism of bone allograft failure, J Bone Joint Surg Br 2002 vol, 84-B no, SUPP III 234 4. Refers to addressable market







# RESEARCH AND DEVELOPMENT

BONESUPPORT's clinical development program focuses on further developing CERAMENT's properties, broadening clinical application areas, plus utilizing CERAMENT's unique drug-eluting properties via the development of combination products which promote bone healing.

A number of combinations with CERAMENT have been studied to supply osteoinductive properties, i.e. the capability to actively stimulate bone healing. Among other research activities, the Company has conducted research in the form of preclinical candidates which combined CERAMENT with bisphosphonates, bone-joint proteins (BMP), bone marrow aspirates (BMA) and demineralized bone matrix (DBM). Priority product candidates for development ourselves are CERAMENT combined with bisphosphonate and CERAMENT combined with DBM, while CERAMENT combined with BMP is a candidate for potential partner development.

Bisphosphonate is a well-established substance for the treatment of osteoporosis and is used to inhibit the activity of osteoclasts, resulting in improved bone healing and bone density. Demineralized bone matrix (DBM), a bone substitute biomaterial, is based on allograft which is reduced in minerals. The material has been shown to have wide usage in conditions and situations where natural bone regrowth is weak.

The total market for DBM amounts to USD 250 million, of which the market in the U.S. constitutes USD 80 million. Combining CERAMENT with DBM would very likely create a product with both

osteoconductive and osteoinductive properties, which entails a therapeutic innovation with unique benefits in the treatment of intractable skeletal injuries, particularly in the trauma segment.

## Clinical evidence – a strategic cornerstone

One of the three cornerstones of the strategy is to deliver industry-leading scientific and clinical evidence that validates the many benefits of CERAMENT. There is already an extensive database of more than 160 research publications and abstracts of preclinical and clinical studies with CERAMENT.

## RESULTS FROM CERTIFY DRIVE CHANGING STANDARDS OF CARE

CERTIFy is a randomized controlled trial conducted at 20 trauma centers in Germany, involving a total of 135 patients. The clinical trial, conducted on tibial plateau fractures, shows that CERAMENT BVF can replace autograft as a treatment standard. The trial confirmed that CERAMENT remodels to bone. In addition, treatment with CERAMENT BVF led to significantly lower patient-perceived postoperative pain and significantly reduced loss of blood. The study, published in The Journal of Bone & Joint Surgery in December 2019, is an important tool for driving

change in the standard of care, which means that more and more clinicians, in consultation with the patient, are choosing CERAMENT over autograft.

## **DE NOVO APPLICATION IN THE U.S.**

In mid-March 2020, CERAMENT G obtained the FDA's "Breakthrough Device" status, a category dedicated to therapies that provide more effective treatment or diagnosis of life-threatening or serious irreversible diseases and at the same time represent a breakthrough technology. In April, BONESUPPORT submitted a De Novo application to the FDA, based on previously published clinical evidence from the Nuffield Orthopaedic Centre, Oxford, among others, for the indication osteomyelitis. Studies from the Nuffield Orthopaedic Centre have shown that the use of CERAMENT G significantly reduces the frequency of re-infection and the need for further surgery. A De Novo application can be made when there is no comparable established alternative ("predicate device") on the market. In February 2021, the FDA requested additional data and clarifications before an approval can be considered. The timetable for a potential market approval regarding the indication bone infection has thus been revised to Q1 2022.

## THE FORTIFY TRIAL

The FORTIFY trial evaluates the ability of CERAMENT G to improve the treatment outcome of patients with open tibia fractures resulting from trauma. That a fracture is "open" means that the skin has been penetrated in conjunction with the trauma. These fractures run a high risk of infection, with inadequate bone healing as a result. The primary effects to be measured in the trial include the absence of deep infection at the fracture site, the absence of additional surgical procedures to promote healing and patient-reported improvement.

The trial, which includes patients at clinics in



both the U.S. and Europe, will form the basis for supporting a planned application to the FDA for PMA (pre-market approval) for a wide range of indications for CERAMENT G, including trauma. Recruitment for FORTIFY was completed in June and the PMA application is expected to be submitted in late 2021. This process will continue according to plan regardless of the company's De Novo application.

## THE SOLARIO TRIAL

BONESUPPORT supports the SOLARIO trial (Short or Long Antibiotic Regimens in Orthopaedics) to investigate whether synthetic bone graft substitute containing antibiotics can lead to shorter treatment times compared to systemic antibiotic treatment, thereby reducing the risk of antibiotic resistance, side effects and additional costs. The trial is led by Oxford University Hospitals NHS Foundation Trust in collaboration with EBJIS - The European Bone and Joint Infection Society. The

SOLARIO trial is a randomized controlled open-label European multicenter trial that is estimated to recruit 500 patients. The first patient was recruited in February 2019 and the trial is expected to end in the first quarter of 2023. If the trial shows a positive outcome, it will certainly contribute to a paradigm shift in the treatment of bone infections

## THE CONVICTION TRIAL

The French CRIOAc¹ healthcare network has initiated CONVICTION, a randomized controlled trial to evaluate the effectiveness of CERAMENT G in the treatment of chronic osteomyelitis. The French Ministry of Social Affairs and Health has made the decision to finance the trial with a research grant from BONESUPPORT partially financing the cost of the products used in the trial.

The trial will evaluate the effectiveness of CERAMENT G in the treatment of osteomyelitis.

The trial is a national multicenter trial and will be conducted by clinicians included in the CRIOAc Network.

A positive outcome from the trial would open up significant commercial possibilities in the French market and it would be possible to obtain improved compensation status.

<sup>1</sup> CRIOAc (Regional Referral Center for Bone and Joint Infection,) is a healthcare network in France that is implemented via a nationwide health ministry program to improve outcomes in the management of bone and joint infection.

## HEALTH ECONOMICS

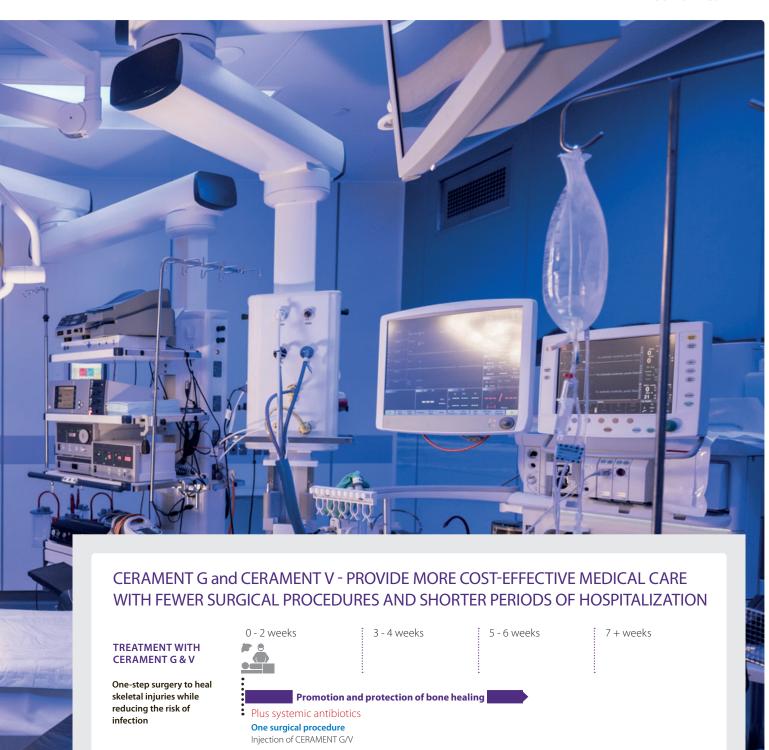
One of the largest challenges when new and innovative medical care technologies are introduced to the market is ensuring that healthcare systems around the world understand their value and include the new treatment in the care that is offered. The value of a treatment is determined in different ways in different countries and BONESUPPORT works on a variety of activities to ensure that the company's products are included in the reimbursement systems in the markets where the products are marketed. During the year, we have strengthened our expertise in the field with an experienced project manager and established collaborations with local partners in strategic markets.

Among the obvious health economic benefits resulting from the clinical benefits CERAMENT offers are a reduction in the utilization of healthcare resources. A reduced number of re-infections and reduced amputation rates resulting from treatment with CERAMENT G and CERAMENT V in single stage procedures naturally lead to fewer re-visits and fewer surgeries and, as a consequence, reduced hospitalization. Another way of looking at the health economic benefits is from the patient and the family perspective – patients with good treat-

ment results have an improved quality of life and the opportunity for an active life. Improved clinical outcomes also have a positive impact on society as a whole – such as less sick leave, reduced need for rehabilitation and care, etc. The significance of health benefits and the calculation models for evaluating the cost-effectiveness of health benefits differ between different healthcare systems. The model we have now established will increase our ability to include the CERAMENT platform in replacement systems more quickly in new markets.







## **TRADITIONAL TREATMENT**

Multi-stage surgery to prevent infection and heal skeletal injuries

Plus systemic antibiotics

1st surgical procedure Placement of non-absorbable antibiotic carrier

Plus systemic antibiotics

Bone healing

## 2nd surgical procedure

Harvest bone graft (autograft)

## 3rd surgical procedure

Removal of non-absorbable antibiotic carrier plus bone transplantation

CERAMENT Gand CERAMENT V free up healthcare resources ...

## SPECIALIST CENTERS TREATING BONE INFECTION HAVE SHOWN THAT FEWER INFECTIONS CONTRIBUTE TO FEWER DAYS OF CARE

When CERAMENT G was introduced in the UK in 2013, the Nuffield Orthopaedic Centre was one of the first clinics to implement CERAMENT G in its treatment algorithm. The Nuffield Orthopaedic Centre is one of the leading clinics in Europe in the field of orthopedics and the treatment of bone infections.

In 2016, Professor Martin McNally presented the clinical results¹ of his first 100 osteomyelitis patients treated with single-stage surgery and CERAMENT G. The results showed an impressive 56% reduction in re-infection rates compared to results presented from previous treatment methods. The positive experiences with CERAMENT led to a joint project between BONESUPPORT and the Nuffield Orthopaedic Centre to study the healthcare economic benefits of the positive clinical results.

The study is based on data from the official statistics database for healthcare in the UK, NHS Hospital Episode Statistics (HES). An analysis was made of all patients who underwent surgical treatment for osteomyelitis between 2013-2017 (over 25,000 patients).

Patients were followed prior to and for two years after surgical treatment. The analysis compared the patients treated at Nuffield after the introduction of CERAMENT G or CERAMENT V in single stage procedures with all patients receiving medical care at other hospitals in the UK.

The preliminary results showed that hospitalization for osteomyelitis surgery was reduced by one third – an average of five days per patient. The analysis also showed that patients treated at the Nuffield Orthopaedic Centre had, on average, 11 fewer days of hospitalization in the two years following surgery. The average daily cost of care per patient at a hospital in the UK is GBP 437.

The preliminary data shows significant benefits in terms of health economics with single stage surgery with the addition of CERAMENT G or CERAMENT V in the treatment of osteomyelitis. The total saving in the number of days of care associated with surgery and subsequent medical care alone could amount to approximately GBP 44 million annually, calculated on the basis of 6,250 patients treated per year.

1. McNally et al. Single-stage treatment of chronic osteomyelitis with a gentamicin-loaded calcium sulfate/hydroxyapatite biocomposite: a prospective series of 100 cases' Bone Joint J 2016:98-B:1289–96

## REDUCED INCIDENCE OF INFECTIONS LEADS TO GREAT SAVINGS FOR HEALTHCARE

Another area where CERAMENT G and CERAMENT V could help reduce healthcare costs is in the treatment of open tibia fractures. Open tibia fractures represent approximately 15 percent<sup>1</sup> of all tibia fractures and have a high incidence of infection, resulting in bones not healing. Bone infections often lead to great suffering for the patient and very high medical costs.

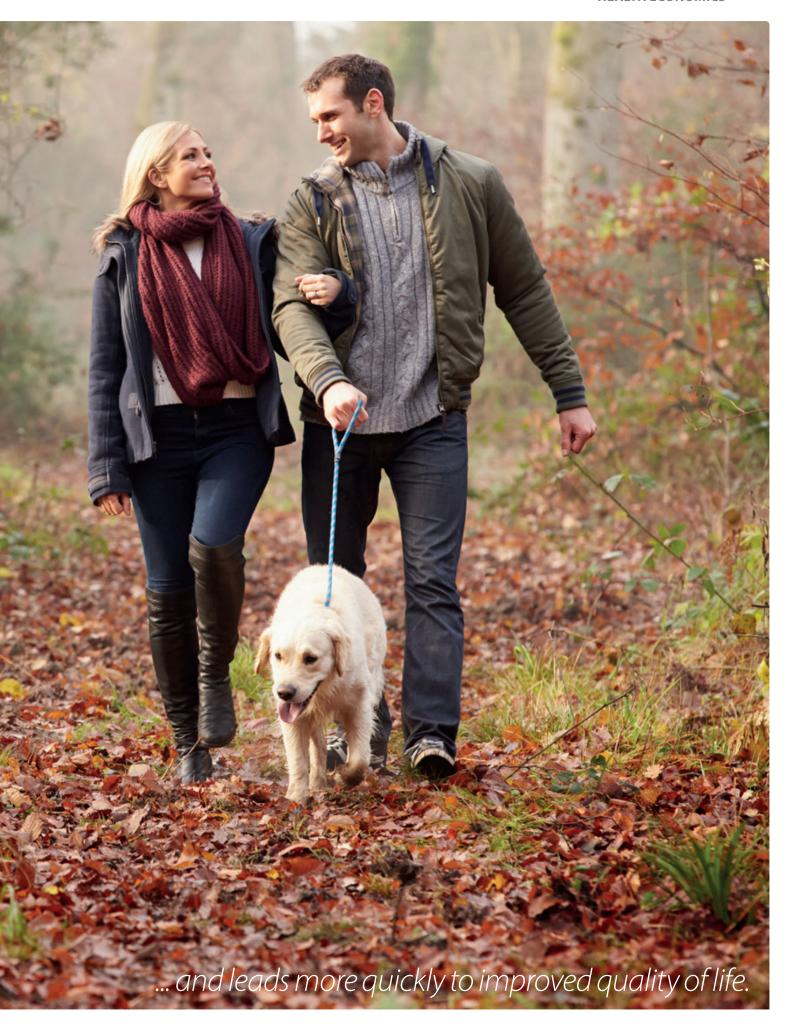
A Belgian study of 358 patients by Hoekstra et al<sup>1</sup>, studied the costs of tibia fractures. The study showed that the healthcare costs for patients who suffered a deep infection were on average five times higher than for those who did not get an infection, which resulted in costs rising from EUR 9.5 thousand to EUR 48.7 thousand.

FORTIFY is designed to create the highest possible evidence level for CERAMENT G and effective management of open tibia fractures, but there are already a number of studies that show that CERAMENT contributes to cost-effective care by reducing

the number of deep infections. One of these is a study by Jahangir et al<sup>2</sup> of 51 patients with severe open tibia fractures treated with CERAMENT G in single stage procedures. In the study, no patient experienced a deep infection. This shows that single-stage treatment with antibiotic-releasing CERAMENT in open tibia fractures can effectively reduce the incidence of costly infections and promote bone healing.

Support for the previously announced Dutch registry study (for fracture-related infections) has been put on hold due to changes in healthcare priorities during the pandemic. Potential new sites for the study are being evaluated.

- Hoekstra et al. Economics of open tibia fractures: the pivotal role of length-of-stay and infection. Health Econ Rev 2017;7:32.
- Jahangir et al. "The use of adjuvant local antibiotic hydroxyapatite bio-composite in the management of open Gustilo Anderson type IIIB fractures. A prospective review." Journal of orthopedics vol. 16,3 278-282.





## Interview with Professor Dirschl

Professor Douglas R. Dirschl, MD is lead investigator in the ongoing FORTIFY study where CERAMENT G is used with the aim of reducing secondary surgical procedures and achieve a lower rate of infection. The FORTIFY Clinical Trial is a prospective, randomized multicenter controlled trial, which will be finalized by the third quarter of 2021. In this interview Professor Dirschl talks about the study and his experience of working with CERAMENT.



## Tell us about your experience of CERAMENT.

I have used CERAMENT BVF – the regular bone void filler – on numerous occasions in treating lower extremity fractures. I must say that I have been pleased with CERAMENT. It was just the product I had been looking for since it hits some very important sweet spots. Its osteoconductive properties are excellent and the material is absorbed by the body at exactly the right rate. Other products are either absorbed too quickly, which means that you lose structural strength, or so slowly that it hampers the formation of natural bone.

## Which are the benefits of CERAMENT from a patient perspective?

The most important benefit is that patients have the potential of a more rapid restoration of function, thereby getting back to their normal activities more quickly.

## How did you get involved in the FORTIFY study?

I had been in contact with BONESUPPORT for a number of years and was asked to participate in the study by the medical team. Since I have used CERAMENT BVF with great satisfaction, it was very easy for me to accept being the principal investigator of the study.

## Could you describe the FORTIFY study?

It is a study where we use CERAMENT G in the management of patients with open tibial fractures. It is a randomized controlled study comparing the outcome of standard care with and without the addition of CERAMENT G at the time of soft tissue closure. The outcome measures we are interested in are the number of re-operations and the number of deep infections.

## What could a successful outcome of the study mean for patients and care givers?

We hope to see that using CERAMENT G results in fewer secondary surgical procedures and a lower rate of infection. For BONESUPPORT, a successful outcome of the FORTIFY study would facilitate an FDA approval to make the product available on the U.S. market for a broad set of indications. Hopefully, this will lead to a breakthrough for treatment.

## When will you have results from the study?

Enrollment in FORTIFY is complete, with 200 patients included. Each patient is followed for twelve months after operation. Once follow-up of all subjects is complete, some time in beginning of the autumn, we will need a number of weeks to analyze the outcomes. I expect that we will be able to present the full study results to the FDA by the end of 2021.

## From your perspective how could CERAMENT G become a solution for the management of osteomyelitis?

One major issue when treating osteomyelitis is that there is often no blood flow in infected areas of bone. The lack of blood flow means that systemic antibiotics treatment may not be effective, since the antibiotics will not reach the infected area. Adding CERAMENT G to the management of osteomyelitis will help solve this issue as the antibiotics is integrated in the bone void filler itself, protecting the osteoinductive properties of CERAMENT G (the bone void filler). The dual mode of action offers the possibility of a single surgical procedure, which is a great benefit.

## CERAMENT G may enable a single stage surgery. How do you see that being perceived by payers and patients?

I believe that payers will appreciate this greatly, as it results in reduced cost and improved patient outcome at the same time. For patients, a single surgical procedure is naturally the preferred choice over multiple procedures, especially if the outcome is likely to be better.

## And for physicians?

For physicians, and for the hospitals as well, CERAMENT G offers the potential of not only a more efficient and more successful treatment method, it also has the benefit of reducing the use of systemic antibiotics. Antibiotic stewardship is a focus area for healthcare in general and systemic antibiotic treatment for osteomyelitis requires higher dosages than CERAMENT G to be effective. Reducing the use of antibiotics is of great benefit overall.

## Which challenges do you see for CERAMENT going forward?

I think that the main challenges for CERAMENT G will be related to market forces, rather than to the performance of the product itself. The bone void filler space in the market in highly competitive; additionally, many surgeons are creatures of habit, such that their adoption of a new bone void filler — even one with the advantages of CERAMENT G — may take some time.

## What do you wish for the future?

As the world's population ages, we will continue to see an increase in fractures in patients with poor bone quality. I believe that augmentation, perhaps using injectable bone void filler, of fracture fixation technology would be very helpful. This field is wide open for investigation and innovation.

## SUSTAINABILITY

BONESUPPORT operates in medical technology, a highly regulated environment that places high demands on products, organization and operations. Sales are made globally, partly directly through our own established subsidiaries and partly indirectly through collaborations with distributors.

## **DEVELOPMENT IN 2020**

In 2020, BONESUPPORT started using a more structured approach to sustainability matters. All employees have been given the opportunity to influence and contribute ideas on how to improve and develop work on sustainability issues, as well as identifying areas where they believe that BONESUPPORT already contributes to more sustainable development. The ambition to give all employees the opportunity to be heard is so that everyone should feel involved in sustainability work and see it as part of their everyday life.

A new pension solution was procured in 2020 where BONESUPPORT took a clear position to encourage employees to choose sustainable funds when placing their occupational pension.

BONESUPPORT will in the future integrate sustainability issues as a natural part of the development projects run within the Group. The goal is that sustainability work should be constant and that the business should be conducted in a responsible manner.

## **GOVERNANCE AND RESPONSIBILITY**

The Board of Directors has overall responsibility for the Group and therefore has ultimate responsibility for the sustainability work of the business. The Board of Directors has adopted policy documents and guidelines regarding, among other things, environmental issues, anti-corruption and respect for human rights, as well as adopting a code of conduct that applies to all employees within the Group. The CEO is responsible for executing the Board's decisions and within the management team Kristina Ingvar, Executive Vice President Quality Management & Regulatory Affairs, has been given responsibility for sustainability work. A working group to deal with sustainability issues has been created within the Group

## **BONESUPPORT'S CODE OF CONDUCT**

BONESUPPORT's Code of Conduct describes the basis for how employees should act, both in contacts with external stakeholders such as customers, partners and hospital employees as well as internally in relation to other employees. All employees must annually read the Code of Conduct and confirm that they have understood the contents. The Code of Conduct is continuously evaluated and is adopted annually by BONESUPPORT's Board of Directors.

There is an external whistleblowing function that employees can use to report suspected bribery, cases of corruption or violations of the Code of Conduct. In order to ensure independence and anonymity, BONESUPPORT has chosen that all reporting and investigation through the whistleblowing function will be handled by an external party.

### **QUALITY**

BONESUPPORT works with medical technology, where good quality is a prerequisite for safe and efficient products.

BONESUPPORT works in the long term with quality issues:

- We comply with international standards for medical devices
- We regularly carry out inspections of contracted manufacturers and other subcontractors
- We are regularly inspected by accredited bodies that certify the business
- Our quality system is certified according to ISO 13485

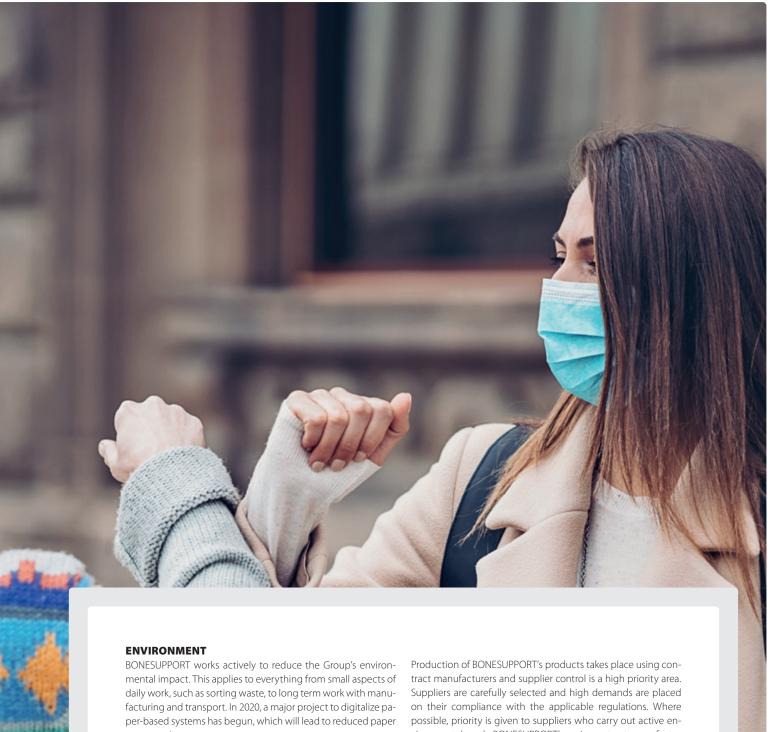
## **OUR VIEW OF ANTIBIOTIC USE**

Antimicrobial Resistance (AMR) is an increasing threat to global public health and collaboration is important in order to counteract this. BONESUPPORT is committed to responsible use of antibiotics and supports antibiotic stewardship.

## **OUR VIEW OF ANIMAL TESTING**

As part of research and development in the medical device industry, it is sometimes necessary to carry out experiments on animals, because this is requested by the responsible authorities. Strict ethical deliberations are made before animal testing is initiated or funded by BONESUPPORT. Alternative methods, such as mathematical modelling or in vitro biological systems, are used if possible. If animal studies are deemed necessary, BONESUPPORT strives to involve as few animals as possible. The protocol is designed to be as gentle as possible for the animals and, in accordance with the legislation, the study protocol is always approved by an ethics committee. BONESUPPORT takes animal welfare very seriously.



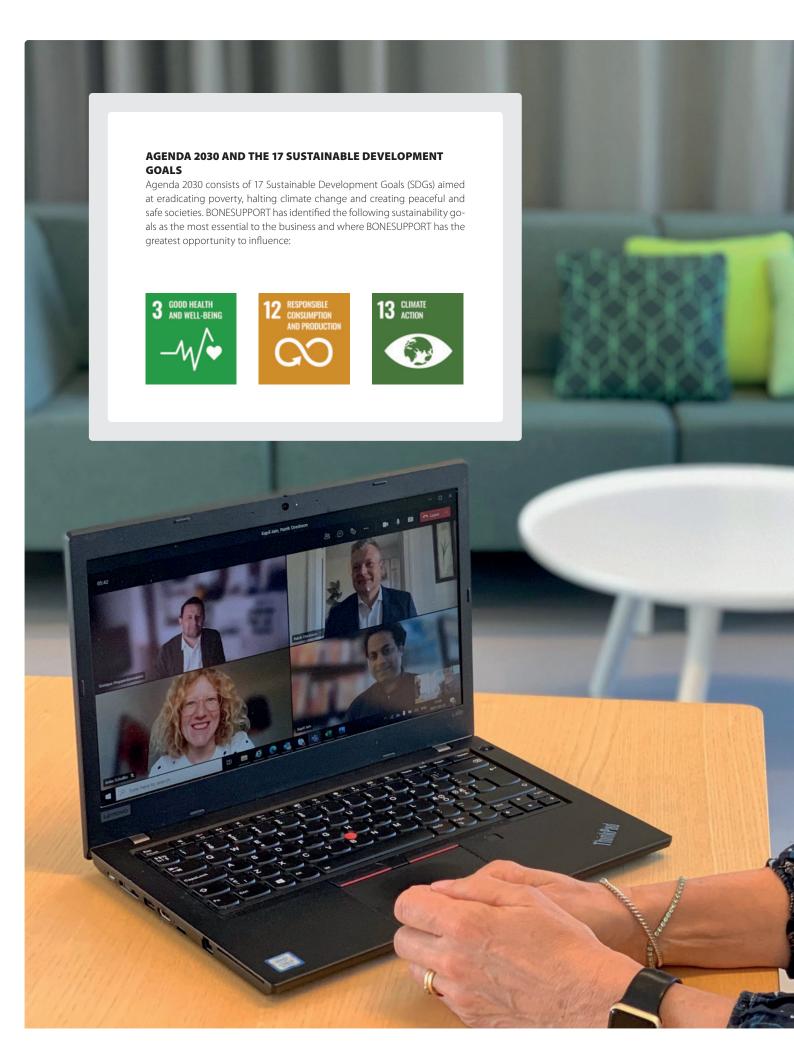


consumption.

From an environmental perspective, the products in the CERAMENT platform have many advantages. The main component of the products is ceramic powder, which is produced using processes that do not cause harmful environmental impacts, such as pollution or hazardous waste. The powder is then mixed with a water-based liquid, which does not contain organic solvents. This means that the product is also safe for the healthcare professionals who handle it. Our development laboratory in Lund is regularly controlled by the environmental administration in Lund Municipality regarding the handling of chemicals and waste.

vironmental work. BONESUPPORT's main contract manufacturer is certified according to the international standard ISO 14001. All materials and components are carefully checked by BONESUPPORT. Production takes place in sterile rooms, strictly controlled environments without any contamination.

In 2021, strategic work will begin with the intention of conducting a review of the entire production chain including transport. The purpose of this is to identify the areas with the greatest environmental impact, in order to be able to target improvement measures where they are most needed.





## **EMPLOYEES**

For the last three years, BONESUPPORT has worked on a program with personal goals for all employees. The COVID-19 pandemic suddenly created new conditions and challenges for both the company and its employees. Through rapid action on the cost side – not least voluntary temporary salary waivers by all employees – we were able to implement significant cost savings. The fact that the entire company took responsibility for a completely unforeseen situation in this way clearly shows the strength of cohesion and the power of the company's culture. Another sign of BONESUPPORT's positive development is that staff turnover decreased during the year.

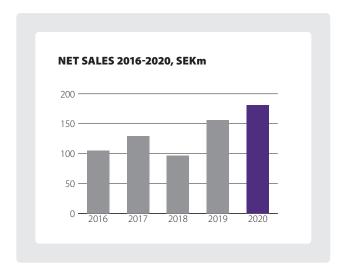
Recruitment in 2020 has been in-house to a greater extent, which has led to significantly reduced costs per recruitment. The methodology has been refined using common tools, which has led to both higher quality in our recruitment and shorter recruitment processes.

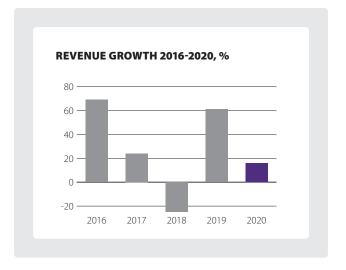
BONESUPPORT works continuously to maintain a good balance in terms of age, gender, ethnicity and time at the company, thereby creating a healthy dynamic and good balance between different individuals and different cultures.

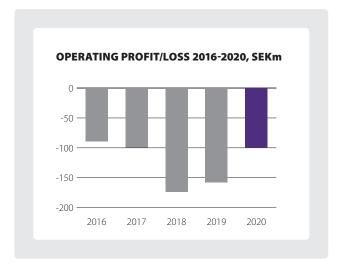
## **GOALS 2021**

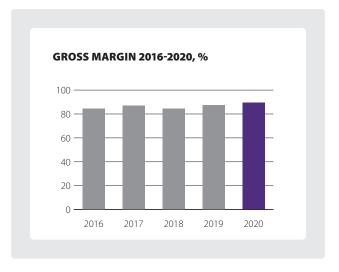
- A main focus of BONESUPPORT is patient and product safety. In 2021, the company will continue to reinforce this work.
- The digitalization work that was vigorously initiated in 2020 will accelerate further in
- Continued focus on further development of a culture with structures that facilitate and simplify the intensive work that BONESUPPORT faces.
- Establish a staff turnover of six percent plus/ minus two percentage points.
- Develop the company's different teams to strengthen their delivery capabilities.
- Ontinue to develop the company's results-oriented culture.

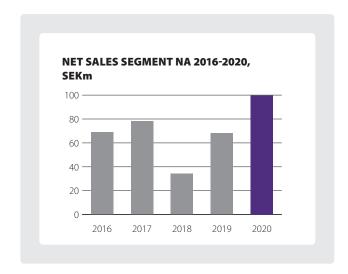
## Operations in overview

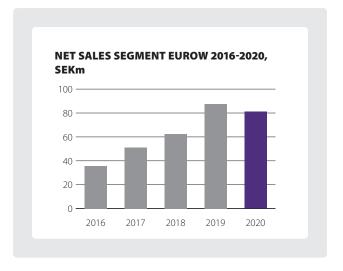












## DIRECTORS' REPORT AND FINANCIAL STATEMENTS 2020

## DIRECTORS' REPORT

## GROUP

### **GENERAL INFORMATION**

BONESUPPORT HOLDING AB (publ), org.no. 556802-2171, registered in Lund, is the parent company of BONESUPPORT AB. BONESUPPORT is a rapidly growing orthobiologics company in the commercial phase that primarily targets the major orthopedic markets in the U.S. and Europe. BONESUPPORT was founded in 1999 and has its registered office in Lund with wholly owned subsidiaries in the U.S., United Kingdom, Germany, Sweden, Denmark, Switzerland, Spain and the Netherlands, as well as a branch in France.

BONESUPPORT develops and commercializes innovative injectable bio-ceramic bone graft substitutes that remodel to the patient's host bone and have the ability to release drugs. BONESUPPORT's bone graft substitutes are based on the proprietary technology platform CERA-MENT. To date, three primary commercial products have been developed:

- CERAMENT® | BVF (BONE VOID FILLER) has significantly improved osteoporosis and other fractures caused by disease or trauma.
- CERAMENT® | G is the first CE-marked injectable ceramic bone graft substitute with the addition of antibiotics (gentamicin). The product is a stage in the treatment of osteomyelitis (skeletal infection) and displays properties such as support and protection for bone healing.
- CERAMENT®V is the first injectable bone substitute with the addition of vancomycin. The product is a stage in the treatment of osteomyelitis (skeletal infection) and displays properties such as support and protection for bone healing.

All three products are marketed in several markets in Europe and the rest of the world, but in the U.S. in 2020 only CERAMENT BVF has been given U.S. Food and Drug Administration (FDA) approval for use. During the spring, we received a breakthrough designation for CERAMENT G for the indication osteomyelitis from the FDA and shortly thereafter we submitted a De Novo application for CERAMENT G. In February 2021, the FDA announced that it wants to see additional data and clarifications, especially regarding the CERAMENT G control group. We will therefore be sending supplementary data during October 2021 and have revised our time schedule for potential market approval for the indication osteomyelitis to the first quarter of 2022.

Our plan to submit a PMA application by the end of 2021 for further indications including trauma remains in place. The application will be based on the results of the randomized controlled trial, FORTIFY. The trial was initiated in 2017 with the aim of evaluating the safety and efficacy of CERAMENT G in open tibia fractures, compared to current standards of care. The trial included the final patient in June 2020. The trial is pro-

ceeding according to plan and the results are expected to be available in the third quarter of 2021.

BONESUPPORT's strategy focuses primarily on continuing to increase sales of current products in existing and new markets, as well as generating additional clinical data through studies and health economic data (HEOR data) to highlight the benefits of CERAMENT.

BONESUPPORT has all the necessary skills to take a medical device from the research and development stage through sales to the end customers. Most of the production is outsourced to third parties. BONESUP-PORT controls the product flow from supplier to customer.

The products are based on an innovative technology backed by a patent portfolio of approximately 100 registered and/or pending patents. BONESUPPORT has fourteen years of documented experience of safety and efficacy and estimates, based on sales data, that more than 55,000 treatments have been performed with its products worldwide. There is great market potential in trauma, chronic osteomyelitis, revision arthroplasty, bone tumors and foot infections due to diabetes. The company's research focuses on continuing to further develop and refine the current technology and to extend it to additional indications through the release of other drugs.

## **MULTI-YEAR OVERVIEW - GROUP**

	2020	2019	2018	2017	2016
Net sales, SEKm	180.9	155.5	96.6	129.3	104.6
Net sales growth, %	16.3	60.9	-25.3	23.6	69.3
Gross profit, SEKm	161.6	135.9	81.5	112.4	88.3
Gross margin, %	89.4	87.4	84.3	87.0	84.4
Operating result, SEKm	-98.6	-158.1	-174.4	-99.3	-88.7
Net loss, SEKm	-101.4	-161.1	-176.4	-128.9	-110.2
Equity, SEKm	398.9	124.3	278.5	450.8	34.3
Net debt, SEKm	-343.3	-81.7	-261.5	-434.7	-31.8
Operating cash flow, SEKm	-100.3	-163.8	-171.6	-107.5	-81.9
Cash at year end, SEKm	353.7	92.1	261.5	533.4	141.5
Earnings per share, SEK	-1.72	-3.10	-3.46	-3.24	-4.26*
Average number of employees**	86	78	72	57	46
Net sales per employee, SEKt	2,103	1,993	1,342	2,268	2,274

- \* Recalculated for aggregation of shares 5:1
- \*\* Expressed as average full-time equivalent.

For definitions and calculations of alternative performance measures see page 77.

### **SIGNIFICANT EVENTS IN 2020**

- In February, the company announced that Patrick O'Donnell was leaving his role as GM & EVP Commercial Operations North America.
- In April, the company submitted a De Novo application to the U.S. Food and Drug Administration (FDA) to obtain market approval for the company's antibiotic-releasing product CERAMENT G. In February 2021, the company received a decision from the FDA requiring additional data.
- In May, the company carried out a directed share issue of SEK 378 million before issue costs.
- Michael Roth took over as GM & EVP Commercial Operations, North America in June.
- In June, the company announced that it was starting its own sales organization in the Netherlands.
- Patient recruitment for FORTIFY ended in June, after approval by the
- In November, the company announced that Simon Cartmell was leaving the company's Board of Directors.

## **IMPACT OF THE COVID-19 PANDEMIC ON BONESUPPORT**

The pandemic has had a major impact on our sales during the year. Non-critical orthopedic surgeries have been postponed and, in addition, a generally lower level of activity in society led to fewer acute trauma operations. Overall, the number of orthopedic surgeries in hospitals and clinics in both the U.S. and Europe was significantly lower in 2020 than in previous years. A concrete example from the Swedish Perioperative Register (SPOR) shows that 91,000 fewer operations were performed in Sweden in 2020 compared to 2019, which corresponds to a decrease of almost 20 percent. The operations postponed in 2020 add to existing long waiting lists for care around the world.

In the longer term, the pandemic has had a limited impact on the demand for BONESUPPORT's products, be it for emergency or planned operations.

## **Expected development**

- A similar impact of the pandemic on BONESUPPORT seen in 2020 can be expected into the beginning of 2021, depending on the extent of the spread of infection, restrictions and healthcare
- In the longer term, the pandemic is expected to have a limited impact on the needs for BONESUPPORT's products, be it emergency or planned operations.

## Selection of measures to protect staff and business operations

- Recommended hygiene procedures and opportunity to work from
- During part of the year, there were reduction in working hours and temporary voluntary salary reductions.
- A well-functioning manufacturing process combined with maintaining high stock security will ensure continued good delivery capacity over the coming quarters.

## Clinical trials

- FORTIFY, in consultation with the FDA, completed the recruitment of new patients prematurely and has entered a new phase of patient
- As previously communicated, the recruitment rate for the SOLARIO trial has been affected by the COVID-19 pandemic and the trial is expected to end in the first quarter of 2023.

- The recruitment rate in other clinical studies is somewhat affected by the pandemic, but this has not, at present, given cause to revise the communicated milestones for the studies.

### REVENUES

Revenue is generated through three channels:

- A combination of our own sales company and distributors in the U.S.
- Direct sales in six countries in Europe
- Sales through distributors in all other markets

During 2020, the focus has been on continued development of the investments in a new distribution structure in the U.S. and in an increased sales force in Europe that were made in 2018 and 2019. During the year, there has been ongoing evaluation of contracted distributors in order to optimize the market presence of CERAMENT and to ensure both geographical coverage and for various indications.

Net sales amounted to SEK 180.9 million (155.5), an increase of 16%. The EUROW segment decreased by 7 percent to SEK 81.1 million (87.4) and the NA segment increased by 47 percent to SEK 99.7 million (68.0).

## **SALES AND MARKETING**

In the U.S., CERAMENT BVF is distributed through BONESUPPORT's new distributor network, which at year-end amounted to more than 40 distributors supported by our commercial platform, of our directly employed and specially trained U.S. sales and marketing organization. At year end, the U.S. commercial organization had 22 (24) employees.

In Europe, BONESUPPORT currently has direct sales with 29 (27) sales representatives in the UK, Germany, Switzerland, Sweden, Denmark and the Benelux countries. BONESUPPORT sells via distributors in Finland, France, Ireland, Italy, Croatia, Norway, Poland, Spain and Austria. BONESUPPORT also sells through distributors in a number of countries outside North America and Europe and has retained the rights to sell to other countries in the rest of the world. During the year, distributors were contracted in Australia and South Africa.

## **RESEARCH AND DEVELOPMENT**

BONESUPPORT's clinical development program focuses on further developing CERAMENT's properties, broadening clinical application areas, and utilizing CERAMENT's unique drug-releasing properties via the development of combination products which promote bone healing.

A number of combinations with CERAMENT have already been studied to supply osteoinductive properties, i.e. the capability to actively stimulate bone healing. Among other research activities, the Company has conducted research in the form of preclinical candidates which combined CERAMENT with bisphosphonates, bone-joint proteins (BMP), bone marrow aspirates (BMA) and demineralized bone matrix (DBM). Prioritized product candidates for own development are CERAMENT combined with bisphosphonate and CERAMENT combined with DBM, while CERAMENT combined with BMP is a candidate for potential partner development.

One of the three cornerstones of BONESUPPORT's strategy is to provide compelling scientific and clinical evidence that validates the many benefits of CERAMENT. There is already an extensive database of more than 160 research publications and abstracts of preclinical and clinical studies with CERAMENT. At the end of 2019, groundbreaking conclusions

were published in the CERTiFy trial, but we also have high expectations for the FORTIFY, SOLARIO and CONVICTION studies.

**CERTIFy** is a randomized controlled trial conducted at 20 trauma centers in Germany, involving a total of 135 patients. The clinical trial, conducted on tibial plateau fractures, shows that CERAMENT BVF can replace autograft as a treatment standard. The trial confirmed that CERAMENT remodels to bone. In addition, treatment with CERAMENT BVF led to significantly lower patient-perceived postoperative pain and significantly reduced loss of blood. The study, published in *The Journal of Bone & Joint Surgery* in December 2019, is an important tool for driving change in the standard of care, which means that more and more clinicians, in consultation with the patient, are choosing CERAMENT over autograft.

In mid-March 2020, CERAMENT G obtained the FDA's "Breakthrough Device" status, a category dedicated to therapies that provide more effective treatment or diagnosis of life-threatening or serious irreversible diseases and at the same time represent a breakthrough technology. In April 2020, BONESUPPORT submitted a **De Novo** application to the FDA, based on previously published clinical evidence from the Nuffield Orthopaedic Centre, Oxford, among others, for the indication osteomyelitis. Studies from the Nuffield Orthopaedic Centre have shown that the use of CERAMENT G significantly reduces the frequency of re-infection and the need for further surgery. A De Novo application can be made when there is no comparable established alternative ("predicate device") on the market. In February 2021, the FDA announced that it would review additional data and clarifications, especially regarding the CERAMENT G control group. We will therefore be sending supplementary data during October 2021 and have revised our time schedule for potential market approval for indication osteomyelitis to the first quarter of 2022.

The **FORTIFY trial** evaluates the ability of CERAMENT G to improve the treatment outcome of patients with open tibia fractures. That a fracture is "open" means that the skin has been penetrated in conjunction with the trauma. These fractures run a high risk of infection, with inadequate bone healing as a result. The primary effects to be measured in the trial include the absence of deep infection at the fracture site, the absence of additional surgical procedures to promote healing and patient-reported improvement. The trial, which includes patients at clinics in both the U.S. and Europe, will form the basis for supporting a planned application to the FDA for a wide range of indications for CERAMENT G, including trauma. Recruitment for FORTIFY was completed in June 2020 and the application is expected to be submitted in late 2021. This process will continue according to plan regardless of the company's De Novo application.

BONESUPPORT supports the **SOLARIO trial** (Short or Long Antibiotic Regimens in Orthopaedics) to investigate whether synthetic bone graft substitute containing antibiotics can lead to shorter treatment times compared to systemic antibiotic treatment, thereby reducing the risk of antibiotic resistance, side effects and additional costs. The trial is led by Oxford University Hospitals NHS Foundation Trust in collaboration with EBJIS - The European Bone and Joint Infection Society. The SOLARIO trial is a randomized controlled open-label European multicenter trial that is estimated to recruit 500 patients. The first patient was recruited in February 2019 and the trial is expected to end in the first quarter of 2023. If the trial shows a positive outcome, it will certainly contribute to a paradigm shift in the treatment of bone infections.

The French CRIOAc healthcare network has initiated **CONVICTION**, a randomized controlled trial to evaluate the effectiveness of CERAMENT G in the treatment of chronic osteomyelitis. The French Ministry of Social Affairs and Health has made the decision to finance the trial with a research grant from BONESUPPORT partially financing the cost of the products used in the trial. The trial will evaluate the effectiveness of CERAMENT G in the treatment of osteomyelitis. The trial is a national multicenter trial and will be conducted by clinicians included in the CRIOAc Network. A positive outcome from the trial would open up significant commercial possibilities in the French market and it would be possible to obtain improved compensation status.

### **STAFF AND ORGANIZATION**

The average number of employees in 2020 was 86 (78) for the Group. Of these, 55 percent (54) worked within in Sales and marketing.

## **EXPENSES AND RESULTS**

## **Gross profit**

As a result of the increased net sales in North America, an increased gross profit of SEK 161.6 million (135.9) was reported, corresponding to a gross margin of 89.4% (87.4).

## Operating expenses

The year was marked by the COVID-19 pandemic and the dampening effect it had on sales but also through the large savings that were implemented.

Sales and marketing costs excluding sales commissions to distributors in the U.S. decreased to SEK 123.8 million (160.1). The decrease of SEK 36.3 million is due to the savings that occurred as a result of the pandemic, partly through a transition to cost-effective meetings on digital platforms, as a direct effect of the pandemic and the restrictions on travel and physical meetings that were applied, and partly through the reductions in working hours and voluntary salary waivers that were introduced during parts of the year. Sales commissions to distributors in the U.S. increased in line with sales growth with SEK 9.4 million to SEK 31.6 million (22.2). Research and development costs decreased to SEK 57.9 million (68.9), the decrease is explained by vacancies and voluntary salary waivers, but also by the FORTIFY trial recruiting the last patient and thus entering a new phase and that the pace of implementation in other trials has been affected by the pandemic. Administration costs increased to SEK 45.5 million (43.3) and, among other things, include increased provisions for incentive programs due to an improved share price. Depreciation amounted to SEK 6.9 million (5.6) of the total operating expenses.

## Operating profit/loss

Operating profit/loss amounted to SEK -98.6 million (-158.1). Operation profit/loss in 2019 was charged with an item affecting comparability of SEK 11.0 million related to repurchase of stock from the previous U.S. distributor. The increase in sales contributed positively to improved gross profit while operating costs decreased as a result of the pandemic and implemented savings.

## Net financial items

Net financial items amounted to SEK -0.4 million (-0.2).

## Loss for the year

For the reasons described above, the loss for the year amounted to SEK -101.4 million (-161.1).

### **INVESTMENTS**

Investments in intangible assets amounted to SEK 2.3 million (2.9) for capitalized development expenses during the year, and SEK 0.3 million (1.5) for equipment and tools.

## **FINANCIAL POSITION AND CASH FLOW**

Cash and cash equivalents amounted to SEK 353.7 million (92.1) at yearend, an increase of SEK 261.7 million since the beginning of the year. The change mainly consists of cash flow from the directed new share issue that was carried out in May, amounting to SEK 361.9 million after issue costs. The change is also explained by cash flow from operating activities amounting to SEK -100.3 million (-163.8) mainly attributable to the operating loss of SEK -98.6 million (-158.1).

At the end of the year, equity amounted to SEK 398.9 million (124.3), of which SEK 40.6 million (32.8) constituted share capital.

## **QUALITY SYSTEMS AND PRODUCT APPROVAL**

BONESUPPORT's quality system complies with the Medical Device Directive 93/42/EEC, ISO 13485 "Medical device-Quality management system-Requirements for regulatory purposes", the FDA's Quality System Requirements and other national regulations. Implementation of the new EU regulatory framework Regulation on Medical Devices 2017/745 is going according to plan.

The company's products are class III products in Europe, undergoing extensive design verification/validation before being assessed and approved for CE marking by the testing body, the British Standards Institute. Prior to that, the Medicines Agency had been consulted for review of the medicinal substance of the product.

## **ENVIRONMENT**

The company's operations are not subject to authorization under the Environmental Code. During the year, the company continued to work with the work environment.

## **OPERATIONAL AND FINANCIAL RISKS**

During 2018 we conducted a significant strategic review of operations. There are many potential application areas for the CERAMENT platform. In our strategy, we have chosen to focus on those areas where there is strong clinical evidence of CERAMENT's therapeutic benefits, i.e. trauma, revision arthroplasty, osteomyelitis, foot and ankle surgery and bone tumors. By concentrating our resources on these indications, we address a market of approximately 650,000 surgical procedures per year.

Our strategy is based on three pillars:

- Innovation
- Leading clinical and health economics evidence
- Effective commercial platform

BONESUPPORT's main operating, as well as financial risks are in market development and the time it takes to create acceptance for the products and thereby generate revenue.

There is currency exposure, primarily to EUR, GBP and USD. Since the revenues are mainly generated in these currencies, a weak SEK has a positive effect.

BONESUPPORT's results have been affected, and will continue to be affected in the future, by several factors wholly or partly outside the company's control. In addition to the above, the following is a description of the main factors that BONESUPPORT believes have affected the results of the business and which can be expected to continue to affect the company's results.

- Risks related to the regulatory environment for medical devices and combination products, such as the high costs of complying with applicable regulatory frameworks, in particular as regards the requirements arising from the EU Directive on medical devices, and corresponding national and regional medical devices legislation, and the effects of amended regulations as well as the consequences resulting from failure to comply with the applicable regulatory framework.
- Risks related to the conduct and outcome of clinical trials, such as time-consuming and costly clinical trials and may be delayed, become more expensive or be discontinued as a result of a number of factors including lack of authorization for the conduct of studies, lack of patient recruitment, undesirable side effects or lack of required clinical efficacy.
- Risks related to a lack of market acceptance from healthcare providers, patients and healthcare payers, for example based on perceived advantages over competing treatments, the presence and extent of side effects and costs of treatment compared to competing treatments, and risks related to a lack of availability of adequate reimbursement systems that may lead to a reluctance to use the company's products.
- Risks that BONESUPPORT does not achieve sufficient revenue or cash flow to finance its operations in the future or is unable to obtain the necessary funding where necessary.
- Risks related to manufacturing, supply and warehousing, such as the company's suppliers and manufacturers not fulfilling their commitments or having their operations curtailed as a result of government intervention, which would risk entailing timeconsuming and costly processes for the company to replace/find new suppliers.
- Risks related to competition and that the company has a limited product portfolio based on a technology platform such that competing products may prove to be better or achieve greater market acceptance or that the company's product candidates do not show sufficient potential for further development, which could lead to failure to obtain market approval.
- Risks related to key employees and qualified personnel, such as the company's dependence on its senior executives and other key personnel and if the company loses key employees, or fails to recruit the necessary personnel, may lead to delays or interruptions in the continued business and product development.
- Risks related to intellectual property rights such as the company's patent protection not being sufficient to adequately protect its operations, that the company infringes the intellectual property rights of third parties or that the company becomes involved in intellectual property disputes.
- Risks related to potential product liability claims and insurance issues such that the company faces significant liability risks if its products or product candidates should cause patients to suffer side effects involving illness, bodily injury or death, and that the company's insurance coverage cannot be maintained or provide adequate protection.
- Risks related to a continued and persistent COVID-19 pandemic and the impact on healthcare systems, our operations and our staff. A more detailed description of risks is given in Note 2. Regarding the Group's internal control and risk management system in connection

with the preparation of consolidated accounts, please refer to the Corporate Governance Report.

### **LEGAL DISPUTES**

BONESUPPORT has no ongoing or known potential legal disputes within the Group.

## **LONG TERM STRATEGIC ACTIVITIES**

BONESUPPORT's strategy can be broken down into the following main activities:

- Produce compelling clinical and health economic data.
- Commercial focus on selected markets and indications.
- Additional data for the De Novo application to the FDA.
- Complete the FORTIFY trial to launch CERAMENT G in the U.S.
- Develop new products that meet market needs in the short, medium and long term.

BONESUPPORT will develop further compelling clinical and health economic data to strengthen its position in the markets for trauma, revisionarthroplasty, chronic osteomyelitis and foot infections due to diabetes.

During the spring, we received a breakthrough designation for CERA-MENT G for the indication osteomyelitis from the U.S. Food and Drug Administration (FDA) and shortly thereafter we submitted a De Novo application for CERAMENT G. In February 2021, the FDA announced that it wants to see additional data and clarifications, especially regarding the CERAMENT G control group. We will therefore be sending supplementary data during October 2021 and have revised our time schedule for potential market approval for the indication osteomyelitis to the first quarter of 2022.

Our plan to submit a PMA application by the end of 2021 for further indications including trauma remains in place. The application will be based on the results of the randomized controlled trial, FORTIFY. The trial was initiated in 2017 with the aim of evaluating the safety and efficacy of CERAMENT G in open tibia fractures, compared to current standards of care. The trial included the final patient in June 2020. The trial is proceeding according to plan and the results are expected to be available in the third quarter of 2021.

The company sees market potential for CERAMENT G in the U.S., based on the reception that the products have had among patients in Europe.

A number of combinations with CERAMENT have been studied to supply osteoinductive properties, i.e. the capability to actively stimulate bone healing. Among other research activity, the Company has conducted research using preclinical candidates which combined CERAMENT with bisphosphonates, bone-joint proteins (BMP), bone marrow aspirates (BMA) and demineralized bone matrix (DBM). Priority product candidates for own development are CERAMENT with bisphosphonate and CERAMENT with DBM, while CERAMENT with BMP is a candidate for potential partner development.

## **PROSPECTS**

The strengthened commercial platform, both in the U.S. and in Europe, the results of our clinical trials and the launch of new products mean that we expect a strong sales increase after the COVID-19 pandemic and an annual sales growth of around 40 per cent.

### THE BOARD OF DIRECTORS AND ITS WORK

Håkan Björklund, Björn Odlander, Lars Lidgren, Tone Kvåle, Lennart Johansson and Simon Cartmell were re-elected at the Annual General Meeting in May 2020. Lennart Johansson was re-elected Chairman of the Board. In November 2020, Simon Cartmell left the company's Board of Directors

The work of the Board of Directors is governed by rules of procedure that are revised and adopted by the Board at least once a year. The Rules of Procedure mainly contain provisions for the work of the Board of Directors, as well as instructions for the division of duties between the Board of Directors and the CEO, as well as instructions for financial reporting. The Swedish Code of Corporate Governance applies. More details are given in the Corporate Governance Report.

## **CORPORATE GOVERNANCE**

The company has chosen to issue the Corporate Governance Report separately to the Annual Report. The Corporate Governance Report can be found on page 69.

## THE BOARD OF DIRECTOR'S PROPOSALS FOR PRINCIPLES OF REMUNERATION TO SENIOR EXECUTIVES

Pursuant to the Swedish Companies Act, the Annual General Meeting shall decide on guidelines for remuneration of the CEO and other senior executives. At the Annual General Meeting on May 19, 2020, guidelines were adopted with primarily the content below. The guidelines that were adopted 2020 apply until further notice.

These guidelines cover the persons who are members of BONESUP-PORT HOLDING AB's ("BONESUPPORT") Group Management. Group management currently consists of nine positions. The guidelines also include any remuneration to Board members for work in addition to board fees.

The guidelines shall be applied to the remuneration agreed, and changes made to already agreed remuneration, after the guidelines have been adopted by the Annual General Meeting 2020. The guidelines do not cover remuneration resolved by the General Meeting, such as fees to Board members or share-related incentive programs.

The Company's starting point is that remuneration shall be at a market and competitive level and shall consist of the following components: fixed salary, variable cash remuneration, pension benefits and other benefits. The level of remuneration for each individual executive shall be based on factors such as duties, expertise, experience, position and performance. In addition, the Annual General Meeting may – and independently of these guidelines – resolve on, for example, share and share price-related remuneration.

In the case of employment relationships governed by rules other than Swedish regulations, appropriate adjustments may be made, in respect of pension benefits and other benefits, to comply with such mandatory rules or established local practice, taking into account, as far as possible, the overall purpose of these guidelines.

The CEO and other senior executives shall be offered a fixed annual salary. The fixed salary shall be determined taking into account the senior executive's expertise, area of responsibility and performance. The fixed salary should be reassessed annually.

In addition to fixed salary, the CEO and other senior executives may, by separate agreement, receive variable cash remuneration. Variable cash remuneration covered by these guidelines shall aim to promote BONESUPPORT's business strategy and long term interests, including its sustainability.

Compliance with criteria for the payment of variable cash remuneration shall be measured over a period of one year. The annual variable cash remuneration may not exceed 75 percent of the fixed annual salary for the CEO and not more than 40 percent of the fixed annual salary of other senior executives, the individual highest level being determined, inter alia, in the light of his or her position. The variable cash remuneration shall not be pensionable, subject to mandatory collective agreement provisions.

The variable cash remuneration shall be linked to one or more predetermined and measurable criteria that may be financial, such as net sales and operating profit, or non-financial, such as qualitative targets. The variable cash remuneration shall be less than 40 percent dependent on non-financial criteria. Clearly and measurably linking the remuneration of senior executives to BONESUPPORT's financial and operational development, promotes the implementation of the company's business strategy, long term interests and sustainability.

Once the measurement period for compliance with the criteria for the payment of variable cash remuneration has been completed, the extent to which the criteria have been met shall be assessed. The Remuneration Committee is responsible for such assessment. Compliance with financial criteria shall be determined based on the latest financial information published by the company. The Board of Directors shall have the possibility to recover, in whole or in part, variable remuneration paid on the basis of information that has subsequently been found to be incorrect.

Pension benefits, including health insurance, shall be defined contribution to the extent that the executive is not covered by a defined benefit pension in accordance with mandatory collective agreement provisions. Premiums for defined contribution pensions, including health insurance, may amount to a maximum of 40 percent of the fixed annual salary.

Other benefits may include life insurance, medical insurance and car

Senior executives shall be employed until further notice or for a certain period of time. In the event of termination by BONESUPPORT, the notice period may not exceed 12 months. Severance pay, in addition to salary and other remuneration during the notice period, may not exceed an amount equal to twelve times the monthly salary. In the event of resignation by the senior executive, the notice period may not exceed six months.

In addition, compensation may be paid for any commitment to restrict competition in order to compensate for any loss of income. Such remuneration shall be paid only to the extent that the former senior executive is not entitled to severance pay. The remuneration shall be based on the fixed salary at the time of termination and shall amount to a maximum of 60 percent of the fixed salary at the time of termination, subject to mandatory collective agreement provisions, and shall be paid for the duration of the anti-competition undertakings, which shall not exceed 12 months after termination of employment.

To the extent that the Board Member performs work on behalf of the company, in addition to the work of the Board of Directors, a market-based consulting fee for such work may be paid to a Board Member or to a company controlled by a Board Member, provided that the services contribute to the implementation of BONESUPPORT's business strategy and the safeguarding of BONESUPPORT's long term interests, including its sustainability.

The Board of Directors has set up a Remuneration Committee. The Remuneration Committee's tasks include preparing the Board's resolution on proposals for guidelines for remuneration to senior executives. The Board of Directors shall prepare proposals for new guidelines at least every four years and shall submit the proposal for resolution at the Annual General Meeting. The guidelines shall remain in force until new guidelines have been adopted by the Annual General Meeting. The Remuneration Committee shall also monitor and evaluate programs for variable remuneration to company management, the application of guidelines for remuneration to senior executives and the current remuneration structures and levels in the company. The members of the Remuneration Committee are independent in relation to the company and company management. The CEO or other members of the executive management may not be present at the Board's discussion of and decisions on remuneration-related matters, to the extent that they are affected by the issues.

The Board of Directors may decide to temporarily deviate from the guidelines in whole or in part, if in an individual case there are special reasons for this and a deviation is necessary to satisfy the company's long term interests, including its sustainability, or to ensure the company's financial viability. As stated above, it is part of the Remuneration Committee's task to prepare the Board's decisions on remuneration issues, which includes decisions to deviate from the guidelines.

In addition to the commitments to pay ongoing remuneration such as salary, pension and other benefits, there is no previously resolved remuneration to any senior executive that has not become due for payment. For further information on remuneration to senior executives, see Note 11.

## PARENT COMPANY

## **REVENUES, LOSS AND FINANCIAL POSITION**

The parent company BONESUPPORT HOLDING AB (publ) owns and administers the shares in BONESUPPORT AB, which in turn owns the shares in the other Group companies. BONESUPPORT HOLDING AB does not undertake any operational activities. BONESUPPORT HOLDING AB was registered on March 15, 2010 in connection with the restructuring of the Group.

In 2020, management fees were charged within the Group. In the Parent Company, SEK 39.4 million (48.3) has been recognized as net sales and SEK 47.5 million (65.6) as administrative costs. The Parent Company's operating expenses amount to SEK 46.2 million (66.0).

During the year, unconditional shareholder contributions of SEK 105.0 million were made to BONESUPPORT AB, compared to SEK 22.0 million the previous year. The profit/loss for the year amounted to SEK -3.1 million (-15.9).

Equity has increased to SEK 1,265.2 million (895.2). Cash and bank balances amounted to SEK 338.1 million (73.6) at the end of the year. Both of these changes are mainly explained by the directed share issue of SEK 361.9 million after issue costs, which occurred in May.

### **FINANCIAL RISKS**

The Parent Company's financial risks are essentially the same as the Group's.

## **OWNERSHIP AT DECEMBER 31, 2020**

The largest shareholders at the end of the year were Health Cap V L.P 10.3%, Stiftelsen Industrifonden 7.5%, Swedbank Robur Fonder 7.1%, State Street Bank and Trust 6.4%, Third Swedish National Pension Fund 5.6%, Avanza Pension 5.6% and Fourth Swedish National Pension Fund 4.9%.

## **THE SHARE**

The company has ordinary shares and class C shares. The quotient book value of the shares is SEK 0.625 per share. As of December 31, 2020, the total number of ordinary shares amounted to 63,764,222 (52,016,342) divided among 5,977 shareholders (2,555), and the total number of class C shares amounted to 1,235,000 (505,000).

According to the Articles of Incorporation, the number of shares shall be not less than 29,000,000 (29,000,000) and not more than 116,000,000 (116.000,000).

## Own shares

BONESUPPORT HOLDING AB holds all class C shares.

Pursuant to authorization from the Annual General Meeting on May 22, 2018, the Board of Directors of BONESUPPORT HOLDING AB resolved to issue 505,000 Class C shares and then immediately repurchase them. The shares were issued and repurchased in accordance with the Performance Share Program Employees 2018/2021 and the performance share program Board of Directors 2018 adopted by the Annual General Meeting on May 22, 2018. SEK 315,625 was paid for the Class C shares in 2019

Pursuant to authorization from the Annual General Meeting on May 14, 2019, the Board of Directors of BONESUPPORT HOLDING AB resolved to issue 730,000 Class C shares and then immediately repurchase them. The shares were issued and repurchased in accordance with the Performance Share Program Employees 2019/2022 adopted by the Annual General Meeting on May 14 2019. SEK 456,250 was paid for the Class C shares during the year.

Their share of the class C shares in the share capital amounts to two (one) percent.

## THE BOARD OF DIRECTORS' PROPOSAL FOR APPROPRIATION

Appropriation Parent Company, SEK				
Unrestricted equity in the Parent Company				
Share premium reserve	1,557,639,419			
Accumulated losses	-329,954,292			
Loss for the year	-3,122,036			
Total unrestricted equity in the Parent Company	1,224,563,092			

The Board of Directors proposes that the share premium reserve, accumulated losses and loss for the year be carried forward.

# CONSOLIDATED INCOME STATEMENT

SEKt	Note	2020	2019
Net sales	4	180,860	155,462
Cost of sales	6, 7	-19,256	-19,587
Gross profit		161,604	135,875
Selling expenses	6, 7, 10, 11, 21	-123,818	-160,139
Sales commissions	6	-31,598	-22,184
Research and development expenses	6, 7, 10, 11	-57,898	-68,878
Administrative expenses	6, 7, 8, 10, 11, 12	-45,492	-43,280
Other operating income	13	12,188	10,667
Other operating expenses	6, 14	-13,547	-10,163
Operating profit/loss		-98,561	-158,102
Loss from financial items			
Financial income	15	5	98
Financial expenses	15	-445	-275
Net financial items		-440	-177
Profit/loss before income tax		-99,001	-158,279
Income tax	16	-2,411	-2,781
Net profit/loss for the year		-101,412	-161,060
Attributable to:			
Equity holders of the Parent		-101,412	-161,060
Earnings per share calculated on earnings attributable to equity h	olders of the Parent		
Earnings per share before and after dilution, SEK	23	-1.72	-3.10

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEKt	2020	2019
Loss for the year	-101,412	-161,060
Other comprehensive income		
Other comprehensive income to be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	-834	115
Other comprehensive income of the year	-834	115
Total comprehensive income of the year	-102,246	-160,945
Attributable to:		
Equity holders of the Parent	-102,246	-160,945
Total comprehensive income of the year	-102,246	-160,945

Other comprehensive income of the year refers in its entirety to exchange differences with no tax effects

# CONSOLIDATED BALANCE SHEET

SEKt	Note	December 31, 2020	December 31, 2019
ASSETS			
Non-current assets			
Intangible assets	18		
Capitalized development expenses		6,115	4,625
Patents		2,725	3,053
Total intangible assets		8,840	7,678
Tangible assets			
Right of use assets	26	11,840	10,385
Equipment and tools	19	3,163	4,200
Total tangible assets		15,003	14,585
Other non-current assets			
Other receivables		0	951
Total other non-current assets		0	951
Total non-current assets		23,843	23,214
Current assets			
Inventories	17		
Raw materials and consumables		30,951	26,987
Finished goods and goods for resale		14,604	12,344
Total inventories		45,555	39,331
Current receivables			
Trade receivables	21, 25	32,108	29,848
Other operating receivables	21, 25	5,317	5,744
Prepaid expenses and deferred income	22	4,658	6,130
Total current receivables		42,083	41,722
Cash and cash equivalents	25, 27	353,737	92,065
Total current assets		441,375	173,118
TOTAL ASSETS		465,218	196,332

# CONSOLIDATED BALANCE SHEET

SEKt	Note	December 31, 2020	December 31, 2019
EQUITY AND LIABILITIES			
EQUITY AND LIABILITIES			
Equity attributable to equity holders of the Parent			
Share capital	23	40,625	32,826
Paid but not registered share issue		0	100
Other paid-in capital		1,557,639	1,191,775
Reserves		-894	-60
Fund for development expenses		5,352	3,552
Accumulated losses including loss for the year		-1,203,823	-1,103,884
Total equity		398,899	124,309
Non-current liabilities			
Leasing debt	25, 26	5,622	5,703
Provisions	24	329	305
Total non-current liabilities		5,951	6,008
Current liabilities			
Leasing debt	25, 26	4,858	4,682
Trade payables	25	12,680	13,649
Income tax payable		4,985	2,330
Other operating liabilities		6,974	4,912
Accrued expenses	22, 25	30,871	40,442
Total current liabilities		60,368	66,015
Total liabilities		66,319	72,023
TOTAL EQUITY AND LIABILITIES		465,218	196,332

# THE GROUP'S CHANGES IN EQUITY

SEKt	Share capital	Paid but not registered share issue	Other paid-in capital	Translation reserve	Fund for development expenses	Accumulated losses	Total equity
As at January 1, 2019	32,373	0	1,187,895	-175	1,801	-943,363	278,531
Comprehensive income							
Loss for the year						-161,060	-161,060
Other comprehensive income							
Exchange differences on translation of foreign							
operations				115	0		115
Total comprehensive income	0	0	0	115	0	-161,060	-160,945
Transactions with equity holders							
Change in fund for development expenses					1,751	-1,751	0
New share issue, employee stock option programs	137						137
New share issue under process, employee stock							
option programs		100	3,880				3,980
New share issue and repurchase of own C-shares	316					-316	0
Share-based payment transactions						2,606	2,606
Total transactions with equity holders	453	100	3,880	0	1,751	539	6,723
As at January 1, 2020	32,826	100	1,191,775	-60	3,552	-1,103,884	124,309
Comprehensive income							
Loss for the year						-101,412	-101,412
Other comprehensive income							
Exchange differences on translation of foreign							
operations				-834			-834
Total comprehensive income	0	0	0	-834	0	-101,412	-102,246
Transactions with equity holders							
Change in fund for development expenses					1,800	-1,800	0
New share issue, employee stock option programs	780	-100	10,569				11,249
Directed share issue	6,563		371,437				378,000
Transaction costs, directed share issue			-16,142				-16,142
New share issue and repurchase of own C-shares	456					-456	0
Share-based payment transactions						3,729	3,729
Total transactions with equity holders	7,799	-100	365,864	0	1,800	1,473	376,836
As at December 31, 2020	40,625	0	1,557,639	-894	5,352	-1,203,823	398,899

# THE GROUP'S CASH FLOW STATEMENT

SEKt	Note	2020	2019
Operating activities			
Operating loss		-98,561	-158,102
Non-cash adjustments	28	20,781	17,556
Interests received		5	98
Interests paid		-6	-36
Income tax paid		-4,970	-5,210
Net cash flows from operating activities before changes in working	g capital	-82,751	-145,694
Changes in working capital			
Increase (-) in inventories		-13,202	-14,613
Increase (-) in operating receivables		-2,916	-8,101
Decrease (-)/increase (+) in operating liabilities		-1,406	4,580
Net cash flows from operating activities		-100,275	-163,828
Investing activities			
Investments in intangible assets	18	-2,312	-2,915
Investments in equipment and tools	19	-346	-1,510
Net cash flows from investing activities		-2,658	-4,425
Financing activities			
New share issue, employee stock options and warrants		11,248	137
Directed share issue		378,000	0
Transaction costs, directed share issue		-16,142	0
Allotted warrants		0	3,980
Repayments of leasing debt	26	-7,768	-5,933
Net cash flows from financing activities		365,338	-1,816
Net cash flows		262,405	-170,069
Cash and cash equivalents as at beginning of the year	25	92,065	261,468
Net foreign exchange difference		-733	666
Cash and cash equivalents as at end of the year	25	353,737	92,065

# PARENT COMPANY'S INCOME STATEMENT

SEKt	Note	2020	2019
Net sales	5	39,371	48,290
Administrative expenses	5, 8, 10, 11	-47,462	-65,568
Other operating income	13	1,642	961
Other operating expenses	14	-331	-1,357
Operating loss		-6,780	-17,674
Result from financial items			
Other interest income and similar income	15	4,624	2,519
Other interest expenses and similar expenses	15	-966	-752
Net financial items		3,658	1,767
Result before taxes		-3,122	-15,907
Income tax	16	0	0
Loss for the year		-3,122	-15,907

Parent Company loss for the year equals comprehensive income

# PARENT COMPANY BALANCE SHEET

SEKt	Note	December 31, 2020	December 31, 2019
ASSETS			
Non-current assets			
Non-current financial assets			
Participations in Group companies	20, 25	831,652	704,652
Receivables on Group companies	25	132,427	125,246
Total non-current financial assets		964,079	851,898
Total non-current assets		964,079	851,898
Current assets			
Current receivables			
Prepaid expenses	22	633	650
Total current receivables		633	650
Cash	25	338,114	73,549
Total current assets		338,747	74,199
TOTAL ASSETS		1,302,826	926,097

# PARENT COMPANY BALANCE SHEET

SEKt	Note	December 31, 2020	December 31, 2019
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	23	40,625	32,826
Paid but not registered share issue		0	100
Total restricted equity		40,625	32,926
Unrestricted equity			
Share premium reserve		1,557,639	1,191,775
Accumulated losses		-329,954	-313,592
Loss for the year		-3,122	-15,907
Total unrestricted equity		1,224,563	862,277
Total equity		1,265,188	895,203
Non-current liabilities			
Liabilities to Group Companies		27,411	19,203
Total non-current liabilities		27,411	19,203
Current liabilities			
Trade payables	25	550	116
Other liabilities		2,598	5,473
Accrued expenses	22, 25	7,079	6,102
Total current liabilities		10,227	11,691
TOTAL EQUITY AND LIABILITIES		1,302,826	926,097

# PARENT COMPANY CHANGES IN **EQUITY**

		Paid but not	Share		
SEKt	Share capital	registered share issue	premium reserve	Accumulated losses	Total equity
As at January 1, 2019	32,373	0	1,187,895	-313,276	906,992
Comprehensive income					
Loss for the year				-15,907	-15,907
Total comprehensive income	0	0	0	-15,907	-15,907
Transactions with equity holders					
New share issue, employee stock option programs	137				137
New share issue under process, employee stock option programs		100	3,880		3,980
New share issue and repurchase of own C-shares	316			-316	0
Total transactions with equity holders	453	100	3,880	-316	4,117
As at January 1, 2020	32,826	100	1,191,775	-329,499	895,202
Comprehensive income					
Loss for the year				-3,122	-3,122
Total comprehensive income	0	0	0	-3,122	-3,122
Transactions with equity holders					
New share issue, employee stock option programs	780		10,569		11,249
Directed share issue	6,563		371,437		378,000
Transaction costs, directed share issue				0	-16,142
New share issue and repurchase of own C-shares	456		-	-456	0
Total transactions with equity holders	7,799	-100	365,864	-456	373,108
As at December 31, 2020	40,625	0	1,557,639	-333,076	1,265,188

# PARENT COMPANY'S CASH FLOW STATEMENT

SEKt	Note	2020	2019
Operating activities			
Operating loss		-6,780	-17,674
Interest received		4,624	2,519
Interests paid		-966	-752
Net cash flows from operating activities before changes in working capi	tal	-3,122	-15,907
Changes in working capital			
Decrease (+)/increase (-) in operating receivables		21,677	-21,429
Decrease (-)/increase (+) in operating liabilities		-12,257	8,108
Net cash flows from operating activities		6,298	-29,228
Investing activities			
Shareholders' contribution		-105,000	-22,000
Net cash flows from investing activities		-105,000	-22,000
Financing activities			
New share issue		11,248	137
Directed share issue		378,000	0
Transaction costs, new share issue		-16,142	0
Allotted warrants		0	3,980
Change in balances towards Group Companies		-9,839	-122,588
Net cash flows from financing activities		363,267	-118,471
Net cash flow	25	264,565	-169,699
Cash as at beginning of the year		73,549	243,247
Cash as at end of the year	25	338,114	73,549

# NOTES

### NOTE 1

GENERAL INFORMATION, ACCOUNTING POLICIES

### **GENERAL INFORMATION**

BONESUPPORT operates within orthopedic products and develops and commercializes innovative injectable bio-ceramic bone graft substitutes that remodel to the patient's host bone and have the ability to release drugs. BONESUPPORT's marketed synthetic bone graft substitutes are CERAMENT BVF, CERAMENT G and CERAMENT V, all of which are based on the innovative and patented CERAMENT technology platform.

BONESUPPORT HOLDING AB (publ) is a limited liability company with its registered office in Lund. The address of the head office is Scheelevägen 19, SE-223 70 Lund.

The Board of Directors approved these consolidated accounts on March 19, 2021 and they will be presented before the Annual General Meeting for adoption on May 20, 2021.

### THE GROUP'S ACCOUNTING PRINCIPLES

The main accounting principles applied at the time of the prepared consolidated accounts are set out below. These principles have been applied consistently for all the years presented unless otherwise stated.

The consolidated accounts are prepared in accordance with International Financial Reporting Standards (IFRS) issued by the International Financial Accounting Standards Board (IASB) as adopted by the EU. Furthermore, the consolidated accounts are prepared in accordance with the Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 1 Supplementary accounting regulations for Groups.

The consolidated accounts are based on historical acquisition values and prepared on a going concern basis.

The company's functional currency is SEK and all amounts are in SEK thousand unless otherwise stated.

# Implementation of new accounting principles

The accounting policies applied include new and changed standards mandatory for the first time for fiscal years beginning January 1, 2020. None of these have had a material impact on the Group's financial statements.

New or amended IFRS standards effective from 2021 or later have not been applied in the preparation of these financial statements. The assessment is that these will not have a material impact on the Group's financial results and finacial position.

In the consolidated income statement, Sales commissions are reported separately on a separate line, unlike previous years' reports when they were included in the line Selling expenses. This amended principle is noted here in accordance with IAS 8 Accounting Policies, changes in accounting estimates and errors.

# **ESTIMATES, ASSUMPTIONS AND ASSESSMENTS**

When preparing the company's financial statements, a number of assessments and estimates, as well as assumptions, have been made that affect the application of accounting policies and the reported amounts in the income statements and balance sheets. Actual outcomes may differ from these estimates and assessments. Estimates and assessments are continuously evaluated and based on historical experience and other factors, including expectations of future events.

The areas of the consolidated accounts containing a significant degree of estimates, assumptions or assessments are described in Note 3.

Current assets and current liabilities are expected to be recovered or paid within one year. Other balance sheet items are expected to be recovered or paid later.

# **BASIS FOR CONSOLIDATION**

The consolidated accounts cover the Parent Company and its subsidiaries. The financial statements of the Parent Company and the subsidiaries included in the consolidated accounts relate to the same period and are prepared in accordance with the accounting principles applicable to the Group. All intra-Group balances, revenues, costs, gains or losses arising in transactions between the companies covered in the consolidated accounts are eliminated in full.

### **SUBSIDIARIES**

Subsidiaries are companies in which the parent holds, directly or indirectly, more than half of the voting rights or otherwise has a controlling interest.

A subsidiary is included in the consolidated accounts from the date of acquisition, which is the date on which the parent company acquired controlling interest, and is included in the consolidated accounts until the date on which that controlling interest ceases.

Subsidiaries are recognized according to the acquisition method. The purchase price for the acquisition of a business consists of the fair value of transferred assets, liabilities and issued shares. The purchase price also includes the fair value of all assets or liabilities that are a consequence of the agreed contingent purchase price. Identifiable acquired assets and assumed liabilities are initially measured at fair value on the date of acquisition.

# TRANSLATION OF FOREIGN SUBSIDIARIES' FINANCIAL STATEMENTS

Items on the balance sheets of subsidiaries are valued in the relevant functional currency, which is the same as the country's local currency. The Group's financial statements are presented in SEK, which is the parent company's functional currency. The income statements and balance sheets of the foreign subsidiaries are translated into SEK. The balance sheets are translated at the exchange rates on the balance sheet date. The profit and loss accounts are translated using the average rates for the year. The exchange differences on translation do not affect profit or loss for the year but are recognized in other comprehensive income in

the consolidated accounts and accumulated. The following exchange rates have been used for translations:

	USD	EUR	CHF	GBP	DKK
Closing day rate December 31, 2020	8.21	10.07	9.29	11.14	1.35
The year's average rate 2020	9.20	10.49	9.80	11.80	1.41
Closing day rate December 31, 2019	9.33	10.45	9.60	12.24	1.40
The year's average rate 2019	9.46	10.59	9.52	12.07	1.42

#### **CASH FLOW STATEMENT**

The cash flow statement has been prepared according to the indirect method. The reported cash flow covers only transactions involving inward or outward payment.

### **REVENUE RECOGNITION**

Revenue is generated through three channels:

- A combination of our own sales company and distributors in the U.S.
- Direct sales in five countries in Europe
- Sales through distributors in all other markets

All revenue from customer contracts is recognized when control of an item is transferred to the buyer. The Group's revenues are mainly generated through one revenue stream, sales of CERAMENT products. Sales income is recognized when the performance obligation is fulfilled. For our customers, the delivery terms of Ex Works BONESUPPORT's warehouse are applied, which means that the control passes to the buyer when the goods leave the warehouse. Some customers keep consignment stocks. In these cases, the revenue is recognized when withdrawals are made from the consignment stocks. Sales in the U.S. are made to end customers and distributors receive commission on generated sales. For distributor markets outside the United States, sales are made to the distributor who is responsible for inventory and sales to end customers.

The sales agreements do not contain any right of return, this applies to both distributors and end customers. Guarantee costs under IAS 37 exist but amount to immaterial amounts, so no provision is made.

In general, 30 days payment terms are applied to the company's direct markets and for sales to distributors, market-adjusted terms of up to 90 days are applied.

# **INTANGIBLE ASSETS**

# Capitalized development expenses and patents:

Expenditure on the development of new products is recognized as an intangible fixed asset once it has received regulatory approval from licensing authorities and if such high-collateral expenditure will bring economic benefits to the enterprise. Capitalized development expenses are recognized as intangible assets and amortization is made from the time the product is ready to use. The amortization period is the useful life, but never longer than ten years. Development expenditure that does not meet these criteria is written off.

Externally acquired patents are activated and reported as patents.

All intangible assets are assessed annually for any impairment requirement.

#### **LEASING**

For leases where BONESUPPORT is the lessee, IFRS 16 Leases is applied. The Company has no leases where it is the lessor.

At the beginning of a contract, it is assessed whether it is a lease that should be recognized as financial leasing. All leases in which the company is a lessee are recognized as financial leases except short term leases and leases where the underlying asset is of low value. For such exemptions, lease payments are recognized as operating expenses on a linear basis over the lease term, unless another method of phasing of the fee gives a more accurate picture of how the economic benefits from the underlying asset are reaped.

The lease liability is initially valued at the present value of future lease payments, discounted at the Group's marginal loan rate. The Group has no external loan financing, so the indication of marginal loan interest is based on discussion with the Group's main bank. After discussion with an external lender, an evaluation has been made of the interest rate for loans the company could take out to finance the acquisition of office property, for example.

Lease payments included in the valuation of lease liabilities include fixed fees less any deduction for benefits associated with the contract; variable lease payments that depend on an index or price; amounts expected to be paid by the lessee under residual value guarantees; the exercise price of an option to purchase if the lessee is reasonably certain to exercise such an option; and penalties payable in the event of termination of the contract, if the lease period reflects that the lessee will exercise an opportunity to terminate the lease.

The lease liability is presented on its own rows in the balance sheet, with a breakdown according to maturity. The lease liability is recognized in subsequent periods by increasing the liability to reflect the effect of interest and decreasing it to reflect the effect of lease payments made. The lease liability is revalued with a corresponding adjustment of the right-of-use asset in accordance with the rules set out in IFRS 16.

The right-of-use asset is initially recognized at the value of the lease liability, with additions for lease payments made at the start date of the agreement and initial direct expenses. The right-of-use asset is recognized in subsequent periods at cost, less depreciation and any impairment losses. The same principles apply to impairment of the right-ofuse asset as those described in the Equipment and Tools section.

The right-of-use asset is depreciated over the estimated useful life or, if shorter, over the agreed lease term. If a contract transfers or is likely to transfer ownership at the end of the lease term, the right-of-use asset is depreciated over the estimated useful life. Depreciation starts at the initial date of the lease. The right-of-use asset is presented on its own row in the balance sheet.

# **EQUIPMENT AND TOOLS**

Equipment and tools are recognized at cost less accumulated depreciation and any impairment losses. The cost includes expenses directly attributable to the acquisition of the asset. Additional expenses are added to the reported value of the asset or recognized as a separate asset, as applicable. Depreciation according to plan is based on the depreciable amount, which consists of the cost less its residual value, which is distributed over the expected useful life. Equipment and tools are depreciated over five years.

Gains and losses on disposal are determined by comparing the proceeds of sales obtained with the carrying amount. The difference is reported in the income statement as other operating income/expenses.

### **IMPAIRMENT OF NON-FINANCIAL ASSETS**

Assets that are written down are assessed for impairment whenever events or changes in conditions indicate that the carrying amount may not be recoverable. An impairment loss is made at the amount by which the carrying amount of the asset exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value reduced by the selling costs and the value in use. When assessing impairment requirements, assets are grouped at the lowest levels where there are separately identifiable cash flows (cash-generating units).

### **FINANCIAL INSTRUMENTS**

A financial asset or liability is included in the balance sheet when the Group becomes a party in a contractual relationship. Financial assets are removed from the balance sheet when the right to receive cash flows from the instrument has expired and the Group has transferred all risks and benefits associated with ownership. Financial liabilities are removed from the balance sheet once the obligation in the contract has been fulfilled.

### Interest-bearing financial assets:

All interest-bearing assets are held to receive ongoing payments. These are initially valued at fair value including transaction costs and then at amortized cost in accordance with the effective interest method. Gains and losses attributable to financial assets are reported in the income statement. Interest rate effects arising from the application of the effective interest method are also reported in the income statement. BONESUPPORT recognizes the following interest-bearing assets in the balance sheet:

- Non-current receivables
- Trade receivables
- Cash and cash equivalents

### Impairment of financial assets:

For interest bearing financial assets, a credit risk reserve is reported and this is based on the future expected losses of the individual assets. For trade receivables, the credit risk reserve is calculated based on the asset's expected loss over its total life. For cash and cash equivalents, the write-down that could be considered is immaterial.

# INVENTORIES

Inventories are reported at the lowest of the acquisition cost and the net realizable value. The acquisition cost is determined using the first in, first out (FIFO) method. The cost of finished goods consists of raw materials, direct salaries and other direct costs. Borrowing costs are not included. The net realizable value is the estimated sales price in operating activities less the sales costs.

### **CASH AND CASH EQUIVALENTS**

Cash and cash equivalents include cash and bank balances

# **FOREIGN CURRENCY**

Transactions in foreign currency are reported at the exchange rate on the transaction date. Monetary assets and liabilities denominated in foreign currency are converted at the exchange rate of the balance sheet date and exchange gains and losses are reported in profit or loss as other operating income/expenses.

### **SHARE CAPITAL**

Transaction costs directly attributable to the issue of new shares are recognized, net of tax, in equity as a deduction after the issue proceeds.

### **EMPLOYEE BENEFITS**

#### Pensions:

The Group only has defined contribution pension plans. The defined contribution pension plans mainly cover retirement pension, disability pension and family pension. The premiums are paid on an ongoing basis during the year by each Group company to separate legal entities, such as insurance companies. The amount of the premium is based on the salary level. Pension costs for the year are included in the income statement.

### **Share-based remuneration:**

The Group has outstanding employee stock options, which are regulated by equity instruments. For detailed descriptions of the programs, please refer to Note 12. Share-based remuneration (employee stock options) is valued based on the market value of the employee stock options at the time the options were assigned. The value of the compensation is not revalued after the assignment date. The total cost is distributed over the vesting period, which is the period during which all the specified vesting conditions are to be met. The cost is recognized as a personnel cost and credited in equity. At each closing date, the Group reassesses how many shares are expected to be earned. Any deviations from the initial assessments that resulted from the review are reported in the income statement and the corresponding adjustments are made in equity.

When the options are exercised, the company issues new shares. Payments received are credited to the share capital (quota value) and other contributed capital when the options are exercised.

Social costs attributable to equity-related instruments as described above are expensed according to the periods during which the services are performed. The cost is calculated based on the same valuation model used when the employee stock options were assigned. The liability for social security contributions incurred is revalued at each closing date on the basis of a new calculation of the contributions that may be paid when the instruments are redeemed. This means that the basis for calculating the social security debt is a new market valuation of the options made at each closing date.

# **DEFERRED TAX**

Deferred tax is recognized on temporary differences. Deferred tax is calculated using a tax rate that has been decided or announced at the balance sheet date and is expected to apply when the deferred tax asset concerned is realized or the deferred tax liability is settled. Deferred tax assets relating to tax deficits are reported to the extent that they are likely to be offset against future taxable surpluses.

### **OPERATING SEGMENTS**

The Group manages and monitors operations in two operating segments: North America (NA) and Europe & Rest of the World (EUROW). Information about operating segment sales and profit or loss is reported in Note 4. Neither assets nor liabilities are followed-up at segment level

as management and follow-up of these are done by management and the Board at Group level.

### THE PARENT COMPANY'S ACCOUNTING POLICIES

The Parent Company prepares its annual report in accordance with the Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities. RFR 2 sets out that the Parent Company's annual report for the legal entity shall apply all EU approved IFRS and statements, as far as possible within the framework of the Annual Accounts Act, and taking into account the connections between accounting and taxation. The recommendation specifies the exceptions and additions to be made compared to IFRS accounting.

The following differences exist between the Group's and the Parent Company's accounting policies:

- Shares in Group companies are recognized in the Parent Company according to the cost method.
- Shares in group companies and receivables on group companies are impairment tested annually, or in case of indication of a decline in value, based on a cash flow forecast over the next five years. For further information see Notes 3 and 20.
- The Parent Company does not apply IFRS 9 and IFRS 16. The Parent Company recognizes financial instruments at accrued acquisition value. There are currently no leases in the Parent Company.
- The Parent Company complies with the Presentation form of the Annual Accounts Act for the income statement and balance sheet, which means, among other things, a different set-up for equity.

### NOTE 2

# FINANCIAL RISK MANAGEMENT

Through its operations, the Group is exposed to various types of financial risks such as market, liquidity and credit risk. Market risk consists mainly of currency risk. BONESUPPORT has an overall financial policy for both the Parent Company and the Group, which regulates the division of responsibilities in financial matters between the Board of Directors, the CEO, CFO and other Group companies. The Board's Audit Committee is tasked with monitoring the design of the financial policy and, if necessary, proposing changes to the Board. The financial policy is characterized by a low level of risk. There have been no changes in financial policy or risk management compared to 2019. The strategy includes continuously identifying and managing risks.

### **MARKET RISK**

Market risk is the risk that the fair value of or future cash flows from a financial instrument vary due to changes in market prices. Market risks are divided into three types; currency risk, interest rate risk and other price risk. The market risk that primarily affects the Group is currency risk.

### **Currency risk**

Currency risk refers to the risk that fair value or future cash flows fluctuate as a result of changes in exchange rates. The exposure to currency risk mainly stems from foreign currency payment flows (transaction exposure) and from the translation of foreign subsidiaries' income statements and balance sheets into SEK (translation exposure). The Group's operations are international and exposed to currency risk, mainly from USD, EUR and GBP.

Approximately 58% (43) of BONESUPPORT AB sales are invoiced in USD, approximately 18% (22) in EUR and approximately 17% (21) in GBP. This is only partly offset by the fact that purchases are also made mainly in EUR. If, all else being equal, USD strengthens or weakens by 5 percent against the Swedish SEK, the Group's profit after tax will be affected by +/- approximately SEK 0.2 million (3.5) based on 2020 transactions, a corresponding strengthening/weakening in EUR gives an impact of +/- 0.3 MSEK (1.0) and for GBP an impact of +/- 0.6 MSEK (0.3).

The foreign subsidiaries invoice and collect costs in their respective local currencies; USD, EUR, GBP, CHF and DKK. The translation risk means that the value of the Group's net investments in foreign currency may be adversely affected by changes in exchange rates when the net assets are consolidated in SEK at the balance sheet date.

The currency risk is mainly attributable to the exposure of outstanding accounts receivable at the end of the reporting period, see Note 21 for distribution by currency. Since the total outstanding accounts receivable consists mostly of USD (about 56%), and subsequently of EUR (about 17%) and GBP (about 14%), currency fluctuations may affect future cash flows. If, all else being equal, USD strengthens or weakens by 5 percent against the Swedish krona, the Group's profit after tax will be affected by +/- SEK 0.9 million (0.6) based on outstanding accounts receivable as of December 31, 2020. The corresponding effect for EUR amounts to +/- 0.3 MSEK (0.4) and for GBP to +/- 0.2 MSEK (0.4).

The Group does not currently use forward contracts or other instruments to reduce currency risk.

The sensitivity analysis in the table below shows the impact on the Group of changes in SEK against the largest currencies. The figures are based on 2020 results and financial position.

- + means a weakening of SEK
- + means a strengthening of SEK

SEKm	+/- 5% USD	+/- 5% EUR	+/- 5% GBP
Transaction risk	+/- 0.2	+/- 0.3	+/- 0.6
Translation risk	+/- 0.1	+/- 0.1	+/- 0.1

### Interest rate risk

Interest rate risk refers to the risk that fair value or future cash flows fluctuate as a result of changes in market interest rates.

As of December 31, 2020, a general increase or decrease in interest rates will not have any impact on the Group's results as there are no bank loans. The effect on the Group's leases is considered marginal.

# Price risk

Price risk refers to the risk that fair value or future cash flows fluctuate as a result of changes in prices.

The Group's sales prices are based on the clinical and health economic benefits validated by a large number of clinical studies and therefore present a low risk of major price movements. The sensitivity to the purchase prices of input goods is mainly managed through long contract times and high stock security.

### **CREDIT AND COUNTERPARTY RISK**

Credit risk refers to the risk that the counterparty in a transaction causes the Group a loss by not fulfilling its contractual obligations. The Group's exposure to credit risk is mainly attributable to accounts receivable. A simplified model is used to calculate credit losses on the Group's accounts receivable. Expected credit losses are calculated based on past events, current conditions and projections of future economic conditions.

The Group's customers consist primarily of hospitals, clinics and distributors with a high credit rating. Accounts receivable are spread across a large number of customers and no single customer accounts for a substantial part of the total accounts receivable. Accounts receivable are spread geographically. The Group considers that the concentration risks are limited. Reversal of estimated customer losses in 2020 amounted to SEK 833 thousand (1,557) and new reserves were made with SEK 69 thousand (16). See also Note 21 for more information about accounts receivable.

The credit risk in cash and cash equivalents is deemed intangible because the counterparties are banks with high credit ratings awarded by international credit rating agencies. As of December 31, 2020, cash and cash equivalents amount to SEK 353,737 thousand (92,065), of which 97% (82) in SEK, 1% (8) in GBP, 1% (5) in USD and 1% (5) in EUR.

The Group's maximum exposure to credit risk is assessed by carrying amounts of all financial assets, see Note 25.

### LIQUIDITY AND FINANCING RISK

Liquidity risk refers to the risk that the Group will have problems meeting payment commitments for financial liabilities. Financing risk refers to the risk that the Group will not be able to raise sufficient funding at a reasonable cost.

Liquidity risk is low because the Group's financial liabilities at the end of 2020 are short term and consist of accounts payable and accrued costs. Payment for the vast majority is due within three months.

The financing risk is assessed based on multi-year liquidity planning, and is about whether the future cash flows are sufficient to run planned operations. In the event that there is a risk that they are not sufficient, the company will balance costs against future revenues in good time and/ or seek alternative financing via borrowings or similar.

### NOTE 3

# ESTIMATES, ASSUMPTIONS AND ASSESSMENTS

When preparing the company's financial statements, a number of assessments and estimates, as well as assumptions, have been made that affect the application of accounting policies and the reported amounts in the income statements and balance sheets. Actual outcomes may differ from these estimates and assessments. Estimates and assessments are continuously evaluated and based on historical experience and other factors, including expectations of future events.

The estimates, assumptions and assessments are described in more detail below.

### **VALUATION OF TAX LOSS CARRY-FORWARDS**

The possibilities for activating deferred tax assets for tax loss carryforwards are examined annually. Deferred tax assets are included only to the extent that there are compelling reasons why they can be offset against future taxable surpluses. For more information on this, see Note

# **VALUATION OF SHARES IN GROUP COMPANIES**

The Parent Company tests annually or more frequently whether there is an indication of a decline in value and whether there is any impairment requirement for shares in Group companies. Recoverable amounts for the shares in Group companies have been determined by calculating the value in use, which requires that comprehensive estimates and assumptions must be made. Discounted forecast future cash flows over the next four years have been calculated in these assumptions, taking into account a discount rate of 9.7% after tax (12.2% before tax). The calculation of discount rates has taken risk-free interest rates, market risk premium and company-specific capital structure and the current tax rate into consideration. Cash flow after the four-year period (the test covers 20 years) is calculated on the basis of an initial forecast growth rate of 40%, with a gradual de-escalation corresponding to 10% per year. The calculated value in use has since been compared with the carrying amount and this comparison shows that there is no need for impairment. A sensitivity analysis where different discount rates were simulated has been carried out. An increase in the discount rate by five percentage points would not entail any impairment requirement. The result of the test shows a surplus and therefore there is no impairment requirement for shares in Group companies.

NOTE 4 **OPERATING SEGMENTS** 

		202	20			201	19	
Profit and loss items	NA	EUROW	Other	Total	NA	EUROW	Other	Total
Net sales	99,727	81,133	0	180,860	68,013	87,448	0	155,462
of which CERAMENT BVF	97,451	12,808	0	110,259	68,013	13,512	0	81,525
of which CERAMENT G and CERAMENT V	0	68,313	0	68,313	0	73,936	0	73,936
of which other	2,275	12	0	2,287	0	0	0	0
Cost of sales	-6,070	-13,186	0	-19,256	-5,654	-13,933	0	-19,587
Gross profit	93,657	67,947	0	161,604	62,359	73,515	0	135,875
Operating costs <sup>1</sup>	-110,478	-54,785	0	-165,263	-118,889	-65,535	0	-184,424
Contribution	-16,821	13,162	0	-3,659	-56,530	7,980	0	-48,549
Other operating items <sup>2</sup>	0	0	-94,902	-94,902	0	0	-109,553	-109,553
Operating result	-16,821	13,162	-94,902	-98,561	-56,530	7,980	-109,553	-158,102
Net financial items	0	0	-440	-440	0	0	-177	-177
Loss before income tax	-16,821	13,162	-95,342	-99,001	-56,530	7,980	-109,730	-158,279

<sup>1</sup> Operating costs comprise selling expenses and research & development costs directly attributable to a segment

BONESUPPORT manages and monitors operations in the North America (NA) and Europe & Rest of the World (EUROW) segments. The sales function follows the segments, where each segment is managed by a responsible business manager, including members of Group Management. Other functions are organized mainly Group-wide, although it is a minor development unit that operates in the United States. The costs included in other operating items are mainly costs for Group functions that cannot be directly allocated to any of the two operating segments. Costs for the option programs are not allocated by segment, as the cost of these programs depends partly on external factors such as valuation of the Company. Therefore, a breakdown by segment could lead to a non-fair allocation if an external factor affects with different impact per segment. The contribution per segment is calculated as net sales minus directly attributable operating costs (see definition above) for the segments.

Markets that delivered more than 10% of net sales during 2020 were United States with 99.7 SEKm (68.0), United Kingdom with 28.4 SEKm (32.6) and Germany with 18.8 SEKm (22.1). Net sales in Sweden amounted to 7.9 SEKm (8.1). No (0) customer represented more than 10% of net sales.

The amounts in the table above are eliminated for Group transactions. Inter company sales from EUROW to NA amounted to 79.3 SEKm (63.8).

The Group's non-current assets are basically based in Sweden.

# NOTE 5

### INTRA-GROUP PURCHASES AND SALES

Intra-group purchases and sales amounted to 321,455 SEKt (364,856). The Parent Company rendered services to Group Companies of 39,371 SEKt (48,290) and purchased services from Group Companies of 30,470 SEKt (49,124).

All intra-group dealings, income, expenses, gains or losses, which arise in transactions between Group Companies are eliminated in total.

# NOTE 6 **EXPENSES BY TYPE**

GROUP	2020	2019
Cost for inventory items	-14,791	-12,565
Personnel costs	-141,226	-140,445
Depreciation and amortization of tangible and		
intangible assets	-8,465	-7,730
Sales commissions	-31,598	-22,184
Other expenses	-95,529	-141,307
Total	-291,609	-324,231

Other expenses mainly concern external services, advertising & public relations, travel expenses and exchange rate losses. Exchange rate losses amount to 15,513 SEKt (10,158).

<sup>2</sup> Other operating items comprise administrative expenses, other operating income & expenses and selling expenses and research & development expenses not directly attributable to a segment

NOTE 7

DEPRECIATION AND AMORTIZATION OF TANGIBLE AND INTANGIBLE ASSETS

GROUP	2020	2019
Capitalized development expenses	823	600
Patents	329	148
Right of use assets	5,970	5,694
Equipment and tools	1,343	1,288
Total	8,465	7,730

Amortization is included in cost of sales.

NOTE 8

COMPENSATION TO AUDITORS

	GROUP		PARENT C	OMPANY
	2020	2019	2020	2019
EY				
Audit fees related to the				
assignment	1,942	3,046	1,403	1,555
Audit related fees	25	0	25	0
Total	1,967	3,046	1428	1,555
Other auditors				
Moore Kingston Smith				
Audit fees related to the				
assignment	228	0	0	0
Other assignments	58	0	0	0
Total	286	0	0	0
Frank Hirth UK				
Audit fees related to the				
assignment	121	180	0	0
Other assignments	675	1,336	0	0
Total	796	1,516	0	0

The above are reported fees and compensation to auditors expensed during the year. Compensation for consultations is reported in cases where the same audit firm holds the audit assignment in the individual company. Audit fees related to the assignment refer to the statutory audit of the annual report and the administration of the Board of Directors and the managing director. Audit related fees refer to the audit of management or financial information to be performed in accordance with statutes, articles of association, or agreements not included in the audit assignment, which shall be concluded in a report, certificate or other document intended for others than the client. Other fees are consultations that cannot be attributed to any of the other categories.

NOTE 9

PERSONNEL (AVERAGE NUMBER)

	2020			
	Men	Women	Total	
PARENT COMPANY:				
Sweden	1	0	1	
SUBSIDIARIES:				
Sweden	12	23	35	
Germany	6	7	13	
USA	16	6	22	
The Netherlands	2	0	2	
Switzerland	2	0	2	
Great Britain	7	3	10	
Denmark	0	1	1	
Total subsidiaries	45	40	85	
Total Group	46	40	86	

	2019		
	Men	Women	Total
PARENT COMPANY:			
Sweden	1	0	1
SUBSIDIARIES:			
Sweden	8	20	28
Germany	5	7	12
USA	14	8	22
The Netherlands	1	0	1
Switzerland	2	0	2
Great Britain	6	5	11
Denmark	0	1	1
Total subsidiaries	36	41	77
Total Group	37	41	78

The number of employees in the tables above represent average full-time equivalents. At the end of the financial year, the Board of Directors was composed of 4 (5) men and 1 (1) woman. The management comprised 6 (6) men and 3 (3) women.

# NOTE 10

SALARY, OTHER COMPENSATION AND SOCIAL SECURITY

	2020		2019	
GROUP	Board & CEO	Other employees	Board & CEO	Other em- ployees
Salary and other				
compensation				
Parent Company	6,915	0	6,535	0
Subsidiaries	0	93,955	0	100,491
Total	6,915	93,955	6,535	100,491

# NOTE 10, cont'd

SALARY, OTHER COMPENSATION AND SOCIAL SECURITY

Social security all employees	2020	2019
Parent Company	2,365	2,473
(of which pension cost)	-1	-1
Subsidiaries	21,975	21,254
(of which pension cost)	-1	-1
Total	24,340	23,727
(of which pension cost)	-1	-1

The amounts in the table do not include share-based remuneration. These are included in Note 11. Social security costs include social security fees on employee stock option benefits.

# NOTE 11

### COMPENSATION TO SENIOR EXECUTIVES AND RELATED PARTY TRANSACTIONS

### Compensation to Chairman of the Board, Board of Directors and Senior Executives, Group

Compensation to the CEO is decided by the Board of Directors on a proposal from the remuneration committee. Senior executives during the year consisted of the CEO and an additional 8 (8) persons. On December 31, 2020 the number of senior executives was 9 (9) including the CEO. For the Group management, market conditions apply to salaries and other employment benefits, which are approved by the remuneration committee.

The CEO's agreement can be terminated by either party with a notice period of 6 (6) months. In case of termination on the part of the Company, a severance pay of 12 (12) months salary (and benefits and average bonus for the last three years will be paid). Other senior executives' contracts have notice periods of up to 6 (6) months.

Most employees have individual, variable bonus systems with measurable goals. Follow-up and evaluation is done quarterly or yearly.

	2020			2019		
	Salaries, fees	Social security	Share-based compensation	Salaries, fees	Social security	Share-based compensation
Lennart Johansson Chairman of the Board from May 2019,						
Director until April 2019	409	526	28	220	69	28
Håkan Björklund Chairman of the Board until May 2019,						
Director from June 2019	195	61	0	375	118	0
Nina Rawal Director until May 2019	0	0	0	185	58	0
Lars Lidgren Director	146	15	0	150	25	0
Björn Odlander Director	170	54	0	175	55	0
Tone Kvåle Director	268	214	28	275	0	28
Simon Cartmell Director until November 19, 2020	211	-118	-84	150	23	55
Emil Billbäck CEO	5,700	4,206	1,137	5,248	2,024	668
Other senior executives 8 (8) persons	12,359	4,131	1,155	14,750	4,019	899

Compensation to the Board of Directors in the table above, excluding the sharebased compensations, are fees that have been paid during 2020. In Note 10, fees expensed regarding 2020 are reported. The guidelines for remuneration to senior executives adopted at the Annual General Meeting 2020 are described in the Director's report and the Corporate Governance Report.

In order to reduce the effects of the COVID-19 pandemic, the Board members made a voluntary waiver for six months amounting to 20 percent of the normal fee, which corresponded to the level of salary waiver made by the CEO and other senior executives.

Bonus to the CEO amounts to 2,527 SEKt (1,653) and to other senior executives to 1.121 SEKt (2.432).

For the current CEO and other senior executives, the Company pays pension premiums according to a scheme where 7% is calculated on salaries up to 7,5 of the current price base, 24% on price base between 7.5-20 and 16% on price base between 20-30. The pension schemes are different since the senior executives, excluding the CEO, are based in 4 (4) different countries. Pension premiums relating to the CEO were paid at 253 SEKt (305) and premiums to other senior executives were paid at 1,080 SEKt (1,165). Board directors have not received any pension.

BONESUPPORT AB has purchased a patent by Professor Lars Lidgren's company Seagles AB – "Case 13-CERAMENT+BMP+anti-catabolic drugs". The agreement was signed in March 2015 and the purchase price for the patent amounts to a total of 2,1 SEKm divided in three installments, of which all have been paid, 900 SEKt in 2019, 660 SEKt in 2017 and 500 SEKt in 2015.

During 2018, BONESUPPORT signed a consultancy agreement with the previous Board Director Simon Cartmell's company Route 2 Advisors Ltd, relating to Life Science. 407 SEKt (615) has been paid during the year.

During the year, BONESUPPORT reimbursed board member Björn Odlander for travel expenses of 9 SEKt (0) through the company Odlander, Fredrikson & Co AB.

# NOTE 12

### EMPLOYEE STOCK OPTION PROGRAMS AND PERFORMANCE SHARE PROGRAMS

At the year end, there are three different employee stock option programs and four performance share programs.

### **Employee stock option programs**

Of the three employee stock option programs, two run over ten years and expire 2022 and 2025 and one program runs over eight years and expires 2024. Each stock option gives the holder the right to acquire 0.2 ordinary share in BONESUPPORT when exercising the option. This at a price of 0.125 SEK, equivalent to 0.625 SEK per share, in the first two programs and 5.30 SEK, equivalent to 26.50 SEK per share, in the third program. The employee stock options are vested according to a schedule in each program. A condition for allotment of options is employment or a contractual relationship with the Company at each vesting date. Of the allocated 25.7 million options, 21.6 million (21.2) options were fully vested before the end of the year. There are no remaining exercisable stock options within the program 2015/2025.

#### Performance share programs

There are three programs for newly recruited employees and one program for two Directors. All programs run over four years; the one that is aimed for the Directors runs until 2021, the other programs run until 2021, 2022 and 2023 respectively. Each savings share gives the opportunity to be allotted a maximum of two, three or four performance shares without payment depending on share price development during the duration of the program for the Directors, and for the other programs also depending on the Company's development in terms of sales and EBITDA during the duration of the program. The performance shares were issued in the form of class C-shares with a subscription price and quota value of 0.625 SEK per share. The program that runs until 2023 has been implemented during the year.

Employee stock options and performance shares are valued at fair value at the date of allocation. The total cost is distributed over the vesting period. The cost is accounted for as personnel cost and is credited to equity. The social security cost is revalued at fair value. When the options are exercised, the Company issues new shares. Payments received on behalf of the shares issued are credited to equity.

# **VALUATION - PERFORMANCE SHARE**

PROGRAM EMPLOYEES 2020/2023	Dec 16, 2020
Dividend	=
Expected volatility	35% - 40%
Interest rate	-0.23%0.39%
Valuation of the share (SEK)	39.61
Valuation model	Black & Scholes/Monte Carlo

# VALUATION - PERFORMANCE SHARE

PROGRAM EMPLOYEES 2019/2022	Dec 10, 2019
Dividend	-
Expected volatility	35%
Interest rate	-0.32%0.57%
Valuation of the share (SEK)	27.10
Valuation model	Black & Scholes/Monte Carlo

# VALUATION - PERFORMANCE SHARE

PROGRAM EMPLOYEES 2018/2021 Nov 7, 2	
Dividend	-
Expected volatility	35%
Interest rate	-0.21%
Valuation of the share (SEK)	10.17
Valuation model	Black & Scholes/Monte Carlo

### **VALUATION - PERFORMANCE SHARE**

PROGRAM BOARD 2018/2021	Jun 20, 2018	
Dividend	-	
Expected volatility	35%	
Interest rate	-0.35%	
Valuation of the share (SEK)	10.17	
Valuation model	Black & Scholes/Monte Carlo	

### **VALUATION - EMPLOYEE STOCK OPTION**

PROGRAM 2016/2024	Nov 9, 2016
Dividend	-
Expected volatility	50%
Interest rate	0%
Subscription price (SEK) - recalculated after share consolidation 5:	1 26.50
Valuation model	Black & Scholes

### **VALUATION - EMPLOYEE STOCK OPTION**

PROGRAM 2012/2022	Jan 1, 2012
Dividend	=
Expected volatility	40%
Interest rate	0%
Subscription price (SEK) - recalculated after share consolidation 5:1	0.63
Valuation model E	Black & Scholes

CHANGES DURING THE YEAR (NUMBER) -		
PERFORMANCE SHARE PROGRAMS	2020	2019
Outstanding at January 1	1,225,000	505,000
Granted during the year	110,000	730,000
Cancelled during the year	-140,000	-10,000
Outstanding at December 31	1,195,000	1,225,000
Exercisable at December 31	0	0

CHANGES DURING THE YEAR (NUMBER) - EMPLOYEE STOCK OPTION PROGRAM		
2016/2024	2020	2019
Outstanding at January 1	2,210,112	2,226,779
Cancelled during the year	-169,167	-16,667
Exercised during the year	-1,541,883	0
Outstanding at December 31	499,062	2,210,112
Evereisable at December 21	456 252	1 021 711

CHANGES DURING THE YEAR (NUMBER) - EMPLOYEE STOCK OPTION PROGRAM		
2012/2022	2020	2019
Outstanding at January 1	2,766,908	3,953,411
Cancelled during the year	-25,000	-84,378
Exercised during the year	-1,760,783	-1,102,125
Outstanding at December 31	981,125	2,766,908
Exercisable at December 31	981,125	2,546,158

# NOTE 12

# EMPLOYEE STOCK OPTION PROGRAMS AND PERFORMANCE SHARE PROGRAMS

Weighted average exercise price for the options that were exercised during the year was 25.41 SEK (0.63) per share.

The expected maturity of the options is based on current expectations and is not necessarily an indication of future actual exercising. The valuation of the share is based on the latest issue price and is fixed. The total cost will change as social security is calculated on the fair value and a new fair value calculation is made quarterly. Volatility, at end of period 40 percent (35), is a conservative valuation of market risk and is based on peer group data due to the share being traded a limited period of time.

During 2020 the cost of employee stock option plans, excluding social security contributions, was recognized as operating expense amounting to 3,729 SEKt (2,498). Accrued social security contributions amounts to 8,100 SEKt (3,475).

# **NOTE 13** OTHER OPERATING INCOME

	GROUP		PARENT COMPANY	
	2020	2019	2020	2019
Exchange rate gains	10,616	9,775	1,642	961
Refunds relating to				
COVID-19	558	0	0	0
Other	1,014	892	0	0
Total	12,188	10,667	1,642	961

# NOTE 14 OTHER OPERATING EXPENSES

	GROUP		PARENT COMPANY	
	2020	2019	2020	2019
Exchange rate losses	13,544	10,158	331	1,357
Other	3	5	0	0
Total	13,547	10,163	331	1,357

# NOTE 15 FINANCIAL ITEMS

GROUP	2020	2019
Interest income	5	98
Total financial income	5	98
	2020	2019
Interest expenses	-445	-275
Total financial expenses	-445	-275
PARENT COMPANY	2020	2019
Interest income, Group	4,624	2,519
Interest expenses, Group	-966	-752
Net financial items	3,659	1,767

# **NOTE 16**

# **INCOME TAX**

#### GROUP

Reported tax	-2,411	-2,781
differences	0	0
Deferred tax related to changes in temporary		
Current tax expense	-2,411	-2,781
Adjustment of taxes attributable to previous years	219	-82
Current tax on loss for the year	-2,630	-2,699
expense of the year:	2020	2019
The following components are included in the tax		

Reconciliation between reported tax and tax expense		
based on applicable tax rate:	2020	2019
Loss before income tax	-99,001	-158,279
Tax according to the applicable tax rate 21.4% (21.4)	21,186	33,872
Difference between Swedish and foreign tax rates	-540	-423
Non tax-deductible items	-918	-7,550
Non taxable income	232	381
Costs that are to be deducted but which are not		
included in the reported result	3,454	0
Current tax attributable to prior years	219	-82
Loss carry forward for which no deferred tax asset has		
been recognized	-26,044	-28,979
Tax expense for the year	-2,411	-2,781

Reported tax expense relate to foreign subsidiaries, mainly the US company that reports positive result before tax. Tax effect from non-deductible costs primarily relates to intercompany profit in inventory and costs for employee stock option programs. No tax is reported in the comprehensive income or directly against equity.

The Group's total loss carry forwards as per December 31, 2020 amount to approximately 1 013 SEKm (890) whereof 114 SEKm (95) refers to the Parent Company. The tax loss carry forwards have no fixed maturity. Deferred tax assets attributable to the loss carry forward has been valued at zero as it is currently not possible to assess when tax losses carry forwards can be utilized. Despite of the positive development at the present, the probability of the Company recognizing profits during the near future is small. When the outlook for this is different, the Company will consider if there are compelling reasons to recognize a deferred tax asset.

### PARENT COMPANY

Reported tax expense:	2020	2019
Tax expense of the year	0	0
Reconciliation between reported tax and tax expense		
based on applicable tax rate:	2020	2019
Loss before income tax	-3,122	-15,907
Tax according to the applicable tax rate 21.4% (21.4)	668	3,404
Non tax-deductible items	-2	-14
Costs that are to be deducted but which are not		
included in the reported result	3,454	0
Loss carry forward for which no deferred tax asset has		
been recognized	-4,120	-3,390
Tax expense for the year	0	0

The Parent Company's prevailing tax rate is 21.4 percent (21.4).

# **NOTE 17** INVENTORIES

Changes in inventory are classified as cost of sales and amount to a cost reduction of 2,200 SEKt (-1,920).

Impairment write-down of inventory to net realizable value due to products with short durability or other impairment risk, amounts to 0 SEKt (48).

# **NOTE 18** INTANGIBLE ASSETS

# **GROUP**

Capitalized development expenses:	Dec 31, 2020	Dec 31, 2019
Opening accumulated acquisition value	13,561	11,544
Disposals for the year	-787	0
Investments for the year	2,313	2,017
Closing accumulated acquisition value	15,087	13,561
Opening accumulated amortization	-8,936	-8,336
Disposals for the year	787	0
Amortization for the year	-823	-600
Closing accumulated amortization	-8,972	-8,936
Closing book value	6,115	4,625
Patents:	Dec 31, 2020	Dec 31, 2019
Opening accumulated acquisition value	3,283	2,383
Investments for the year	0	900
Closing accumulated acquisition value	3,283	3,283
Opening accumulated amortization	-229	-80
Amortization for the year	-329	-149
Closing accumulated amortization	-558	-229
Closing book value	2,725	3,054

Regarding the purchased patent, see Note 11.

# **NOTE 19 EQUIPMENT AND TOOLS**

GROUP	Dec 31, 2020	Dec 31, 2019
Opening accumulated acquisition value	6,824	5,402
Investments for the year	346	1,510
Disposals for the year	0	-191
Translation difference	-221	103
Closing accumulated acquisition value	6,949	6,824
Opening accumulated depreciation	-2,624	-1,517
Disposals for the year	0	191
Depreciation for the year	-1,343	-1,288
Translation difference	181	-10
Closing accumulated depreciation	-3,786	-2,624
Closing book value	3,163	4,200

# NOTE 20 PARTICIPATIONS IN GROUP COMPANIES

PARENT COMPANY	Dec 31, 2020	Dec 31, 2019
Opening accumulated acqusition value	1,024,438	1,002,438
Shareholders contribution	105,000	22,000
Closing accumulated acquisition value	1,129,438	1,024,438
Opening accumulated write-down	-297,786	-297,786
Closing accumulated write-down	-297,786	-297,786
Closing book value	831,652	726,652

# NOTE 20, cont'd

# PARTICIPATIONS IN GROUP COMPANIES

	Share of equity %	Number of shares		Book value Dec 31, 2019	Corporate reg. no.	Registered office
BONESUPPORT AB	100	1,000	831,652	726,652	556800-9939	Lund

### SUBSIDIARIES OF BONESUPPORT AB:

	Share of equity %	Number of shares	Book value Dec 31, 2020	Book value Dec 31, 2019	Corporate reg. no.	Registered office
BONESUPPORT Inc.	100	100	69	69	98-0539754	Delaware
BONESUPPORT GmbH	100	1,000	0	0	HRB 80228	Frankfurt
BONESUPPORT BV	100	18,000	183	183	34377023	Amsterdam
BONESUPPORT Switzerland GmbH	100	20,000	171	171	CHE-474.771.411	Zürich
BONESUPPORT UK Ltd	100	1	0	0	10352673	London
BONESUPPORT ApS	100	500	69	69	40081135	Kongens Lyngby
BONESUPPORT, S.L.U.	100	3,500	36	36	B67244988	Barcelona
BONESUPPORT Incentive AB	100	100,000	840	840	556739-7780	Lund

# NOTE 21

# TRADE RECEIVABLES AND OTHER RECEIVABLES

The Group's customers are mainly hospitals and clinics. Credit risk is considered low for the vast majority of customers. The Group shows a history of very low realised credit losses.

	GRO	UP	PARENT C	OMPANY
	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
Trade receivables	32,108	29,848	0	0
Other receivables	5,317	5,744	132,427	125,246
Total	37,425	35,592	132,427	125,246

0.1				
Other receivables				
above refer to:	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
Receivables on				
Group companies	0	0	132,427	125,246
VAT receivable	2,021	1,887	0	0
Other	3,296	3,857	0	0
Total	5 217	5 7/1/1	122 /27	125 246

	GROUP		
Credit risk exposure:	Dec 31, 2020	Dec 31, 2019	
Trade receivables not past due, gross amounts	19,176	17,252	
Expected credit loss	0	0	
(Expected credit loss, %)	0%	-100%	
Trade receivables past due, gross amounts	13,001	13,526	
Expected credit loss	-69	-930	
(Expected credit loss, %)	1%	7%	
Total trade receivables	32,108	29,848	

Improved internal control and strengthened processes have led to a reassessment of earlier provisions which has impacted the result with 883 SEKt (1,557) due to reversal of impaired trade receivables.

Principles for measurement of expected credit losses are described in Note 1.

Due date for trade receivables past due but not		
written off:	Dec 31, 2020	Dec 31, 2019
Less than 1 month	5,521	4,942
1-3 months	4,668	3,390
More than 3 months	2,743	4,267
Total	12,932	12,599
Changes in credit risk provision:	2020	2019
As of January 1	930	2,449
Provision for bad debts	69	16
Reversal of previous provisions for bad debts	-833	-1,557
D 6 11 6 1 1 1 1 1	-97	0
Recovery of provision for bad debts		
Recovery of provision for bad debts  Translation difference	-1	22

No provision for expected credit losses have been made for other receivables since it is considered immaterial. No credit risk provision has been made for receivables on Group companies.

The four largest customers represent 13% (9) of total trade receivables. The single largest customer represents 5 percent (3).

Group's trade receivables per currency:	Dec 31, 2020	Dec 31, 2019
USD	17,932	12,058
SEK	1,205	1,117
EUR	5,664	7,229
GBP	4,428	7,146
DKK	1,803	942
CHF	1,076	1,356
Total	32,108	29,848

# NOTE 22 ACCRUALS AND PREPAID ITEMS

GROUP

PARENT COMPANY

_	GROU	P	PAREINIC	JIVIPANT
	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
Prepaid expenses				
and deferred income				
Deferred income	1,299	0	0	0
Prepaid insurance	1,138	1,167	513	646
Other prepaid				
expenses	2,221	4,963	120	4
Total	4,658	6,130	633	650
Accrued expenses				
Accrued social				
security contributions				
for employee stock				
options	8,100	3,515	3,416	0
Accrued bonus				
including social				
security contributions	8,234	9,908	1,572	2,872
Accrued holiday				
including social				
security contributions	5,555	4,938	622	531
Accrued pension	1,822	1,092	61	74
Other accrued social				
security contributions	1,525	1,340	361	356
Repurchase of stock				
items	0	11,000	0	0
Other accrued				
expenses	5,635	8,649	1,047	2,269
Total	30,871	40,442	7,079	6,102

# NOTE 23 SHARE CAPITAL AND EARNINGS PER SHARE

Total number of shares, quotient value 0.625 SEK	
(0.625)	64,999,222
Number of shares December 31, 2018	51,795,917
Share issue, C-shares	505,000
Conversion of employee stock options 2019	220,425
Number of shares December 31, 2019	52,521,342
Share issue, C-shares	730,000
Share issue, ordinary shares	10,500,000
Conversion of employee stock options 2020	660,532
Conversion of warrants 2020	587,348
Number of shares December 31, 2020	64,999,222
Number of votes	63,887,722

The total number of shares at the end of the year is 64,999,222 (52,521,342) of which 63,764,222 (52,016,342) are ordinary shares and 1,235,000 (505,000) are series C-shares. The share capital amounts to 40,625 SEKt (826). During 2020, 660,532 (220,425) shares were issued from exercise of employee stock options.

# NOTE 23, cont'd

SHARE CAPITAL AND EARNINGS PER SHARE

# **EARNINGS PER SHARE - BEFORE DILUTION**

Earnings per share before dilution is calculated using the following results and number of shares:

	2019	2018
Loss for the year, SEKt	-101,412	-161,060
Weighted average number of shares, thousands	59,081	51,889
Earnings per share before dilution, SEK	-1.72	-3.10

### **EARNINGS PER SHARE AFTER DILUTION**

BONESUPPORT has in total 657,135 (2,205,614) potential shares in form of employee stock options and warrants. Of the number of potential shares as of end 2020, 361,096 (1,210,210) are warrants. During 2018, 361,096 warrants were issued to management. The rest of the potential shares are employee stock options, 296,039 (995,404).

However, as the result is negative, dilution does not affect earnings per share.

# NOTE 24 PROVISIONS

The Group has capitalized direct pensions that has been presented net in the balance sheet. Payroll tax relating to the pensions has been recorded as a provision.

	2020	2019
As of January 1	305	289
Re evaluation	24	16
As of December 31	329	305

# NOTE 25

# CLASSIFICATION OF FINANCIAL INSTRUMENTS

The Group's financial assets and liabilities valued at amortized cost:

	Dec 31, 2020	Dec 31, 2019
Financial assets:		
Trade receivables	32,108	29,848
Other receivables	436	3,937
Cash and cash equivalents	353,737	92,065

Financial liabilities:		
Leasing debt	10,480	10,385
Trade payables	12,680	13,649
Accrued expenses	5,636	19,649

The Parent Company's financial assets and liabilities:

	Dec 31, 2020	Dec 31, 2019
Financial assets:		
Participations in Group companies	831,652	726,652
Receivables on Group companies	132,427	125,246
Cash	338,114	73,549

Financial liabilities:		
Trade payables	550	116
Accrued expenses	1,047	1,879

All financial liabilities are valued at amortized cost. The fair value of financial assets and liabilities is estimated to be in accordance with the booked value due to the short maturity. The Parent Company values all financial assets except participations in Group companies at amortized cost. Accrued expenses are specified in Note 22. For information on interest income on financial assets, see Note 15. Losses on financial assets, recognized in the income statement as credit losses are described in Note 21.

# NOTE 26 LEASING

The Group has lease agreements with Första Fastighets AB IDEON (Wihlborgs) in Sweden and John Hancock Life Insurance Company/John Hancock Life & Health Insurance Company in USA for the lease of office and warehouse space. In addition, the Group has contracts with a number of suppliers for car leasing and a leasing contract with ATEA regarding the rental of computers and other IT equipment. All items are used in the Company's daily operations. The lease period for premises extends between three and five years, for cars between three and four years and for computers and other IT equipment for three years. The terms of the agreement are market-based and none of the contracts require the Group to maintain any financial key figures.

# NOTE 26, cont'd

LEASING

No leasing contracts last longer than five years.

The right of use assets and the leasing debt and how their book values have changed during the year is summarized below:

### GROUP - RIGHT OF LISE

GROOF - KIGHT OF USE				
ASSETS	Buildings	Cars	Equipment	Total
Opening accumulated				
acquisition value	12,571	3,202	306	16,079
New leasing objects	3,753	2,150	1,522	7,425
Disposals	-119	-99	0	-218
Closing accumulated				
acquisition value	16,205	5,253	1,828	23,286
Opening accumulated				
depreciation value	-4,339	-1,253	-102	-5,694
Disposals	119	99	0	218
Depreciation for the year	-3,879	-1,726	-365	-5,970
Closing accumulated				
depreciation	-8,099	-2,880	-467	-11,446
Closing book value	8,106	2,373	1,361	11,840

GROUP - LEASING DEBT	2020	2019
Opening balance	10,385	0
Transition effect	0	14,145
Debt for new leasing objects	7,426	1,256
Repayment of debt	-7,768	-5,933
Interest expense	437	239
Translation difference	0	678
Closing balance	10,480	10,385
of which non-current leasing debt	5,622	5,703
of which current leasing debt	4,858	4,682

When calculating the liability of remaining payments, an interest rate of six percent has been applied as discount rate. There is no marginal borrowing rate since the Group has no loans. After discussing with external lenders, a reasonable borrowing rate for a real estate loan has been evaluated. A development company carries a high risk premium why six percent has been considered reasonable.

The Group's leasing debts have the following, undiscounted maturities:

GROUP - LEASING DEBT PER MATURITY	Dec 31, 2020	Dec 31, 2019
Within one year	6,321	6,340
Between one and two years	4,947	2,670
Between two and three years	2,340	2,246
Between three and four years	1,053	1,368
Between four and five years	0	433
Sum	14,661	13,057

# NOTE 26, cont'd

LEASING

The amounts with which leasing has been reported in the income statement are as follows:

GROUP	2020	2019
Depreciation right of use assets	5,970	5,694
Interest expense for leasing debt	437	239
Fees for leasing agreements of low-value assets	0	15
Total	6,407	5,948

The Parent Company is not engaged in any operational lease contracts.

Leasing is included in the Group's total cash flow with 437 SEKt (239) regarding interest payments and 7,331 SEKt (5,933) regarding repayment of borrowings.

# NOTE 27

# PLEDGED SECURITIES AND CONTINGENT LIABILITIES

### **PLEDGED SECURITIES**

The US subsidiary BONESUPPORT Inc. has provided a guarantee for its rented facilities of 56 USDt (56), corresponding to 460 SEKt (523). The Parent Company guarantees a corresponding amount.

BONESUPPORT AB has capital-invested direct pensions amounting to 979 SEKt (979). The Parent Company has pledged collateral amounting to the corresponding amount.

At the end of 2020 and 2019, the Group and the Parent Company had no other contingent liabilities.

# NOTE 28

ITEMS NOT INCLUDED IN THE CASH FLOW

GROUP - ITEMS NOT INCLUDED IN CASH		
FLOW	2020	2019
Depreciation regarding right of use assets	5,970	5,694
Other depreciation and amortization	2,495	2,036
Repurchase of items from previous distributor	0	11,000
Costs for employee stock option programs	3,729	2,605
Unrealized exchange rate differences	8,531	-1,601
Write-down (or release thereof) on trade		
receivables	32	-1,618
Other	24	-560
Total	20,781	17,556

# **NOTE 29**

# EVENTS AFTER THE CLOSING DAY

BONESUPPORT was moved from the Small Cap to the Mid Cap segment on Nasdaq Stockholm on January 4, 2021.

The recruitment rate to ongoing studies has been influenced which has led to a changed end date for the SOLARIO study: Q1 2023.

The beginning of 2021 has been marked by the COVID-19 pandemic gaining new momentum with fewer emergency and planned operations as a result.

The US Food and Drug Administration (FDA) informed BONESUPPORT in February 2021 that the Company's De Novo application for CERAMENT G for the indication bone infection requires additional information and clarification, which means that the time for a potential De Novo approval is moved forward and calculated to first quarter 2022.

# NOTE 30

# PROPOSAL FOR APPROPRIATION - PARENT COMPANY

#### SEK

Unrestricted equity in the Parent		
Company	Dec 31, 2020	Dec 31, 2019
Share premium reserve	1,557,639,419	1,191,775,472
Retained earnings	-329,954,292	-313,591,392
Loss for the year	-3,122,036	-15,906,650
Total	1,224,563,092	862,277,430

The Board of Directors propose that the share premium reserve, retained earnings and loss for the year should be carried forward. The proposal will be presented at the Annual General Meeting on May 20, 2021.

# THE BOARD'S ASSURANCE

The Board of Directors and the CEO assure that the consolidated accounts have been prepared in accordance with international accounting standards IFRS as adopted by the EU and give a true and fair view of the Group's position and results. The Annual report has been prepared in accordance with generally accepted accounting standards and gives a true and fair view of the parent company's position and results.

The Annual report of the Group and the Parent Company gives a true and fair view of the development and the Group's and the Parent Company's operations, position and results, and describes significant risks and uncertainties facing the Parent Company and the companies that are part of the Group.

Lund April 13, 2021

Lennart Johansson Chairman of the Board

Håkan Björklund Board member

Tone Kvåle Board member

Lars Lidgren Board member Björn Odlander Board member

Emil Billbäck CEO

Our audit report was delivered on April 13, 2021

Ernst & Young AB

Ola Larsmon Authorized Public Accountant

# AUDITOR'S REPORT

# TO THE GENERAL MEETING OF THE SHAREHOLDERS OF BONESUPORT HOLDING AB (PUBL), CORPORATE IDENTITY NUMBER 556802-2171

### REPORT ON THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS

### **Opinions**

We have audited the annual accounts and consolidated accounts of BONESUPPORT HOLDING AB (publ) for the year 2020. The annual accounts and consolidated accounts of the company are included on pages 29-63 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the parent company as of 31 December 2020 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2020 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Our opinions in this report on the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

### **Basis for Opinions**

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

# **KEY AUDIT MATTERS**

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

We have fulfilled the responsibilities described in the Auditor's responsibilities for the audit of the financial statements section of our report, including in relation to these matters. Accordingly, our audit included the performance of procedures designed to respond to our assessment of the risks of material misstatement of the financial statements. The results of our audit procedures, including the procedures performed to address the matters below, provide the basis for our audit opinion on the accompanying financial statements.

### Revenue recognition

### Description

Net sales for 2020 amounts to KSEK 180.860 in the consolidated income statement. The revenue recognition principles are described in Note 1. Revenues are reported based on the compensation expected to be received by the group in exchange for transfer of promised goods or services to a customer, exclusive of any amounts collected on behalf of third parties (such as sales taxes), at the point at which the control over the good has transferred to the customer. The revenues arise primarily from one revenue stream, sales of goods, via three channels with different sales conditions; sales in the United States with a combination of sales entity and distributors, direct sales in five countries in Europe and sales via distributors on all other markets. We have thus considered revenue recognition to represent a key audit matter.

A description of the principles for revenue recognition is included in Note 1 and information on operating segments in Note 4.

### How our audit addressed this key audit matter

We have evaluated the company's revenue recognition process through our audit. Amongst other we have tested the company's recorded revenue transactions, audited credit notes and accounts receivable, performed data analytics and performed analytical review procedures. Moreover, we have analyzed sales compared to the prior year and movements in the recorded revenues compared to expectations, audited customer agreements, conducted sample tests on accruals at financial statement closing and conducted tests of incoming payments.

We have audited disclosures in the annual report.

### Shares in subsidiaries

### Description

The carrying amount of shares in subsidiaries per 31 December 2020 amounts to KSEK 831.652 in the parent company's balance sheet, which corresponds to 64% of total assets in the parent company. The company annually and at indication of impairment that reported values do not exceed the estimated recoverable amount. The recoverable amount is determined by a present value calculation of future cash flows. Future cash flows are based on management's forecasts and include a number of assumptions, including earnings, growth, investment needs and discount rates.

Changes in assumptions have a major impact on the calculation of the recoverable amount and the assumptions applied by the company may therefore be of major importance for the assessment of impairment. We have therefore considered the reporting of shares in subsidiaries as a key audit matter.

A description of the impairment test is included in the section on assessments, estimates and assumptions in Note 3 and information about shares in subsidiaries is included in Note 20.

### How our audit addressed this key audit matter

In our audit we have evaluated and tested the company's process for establishing impairment tests, amongst other by evaluating accuracy in previous forecasts and assumptions. We have also made comparisons with other companies to evaluate the fairness of future cash flows and growth assumptions, and with the help of our valuation specialists evaluated the applied discount rate and assumptions about long-term growth. Moreover, we have examined the model and method for carrying out impairment test. We have audited disclosures in the annual report.

# Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-28, 68 and 73-77. The remuneration report for the financial year 2020, which will be issued after the date of this auditor's report, also constitutes other information. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated

If we, based on the work we have performed concerning the other information that we obtained prior to the date of this auditor's report, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

When we read the remuneration report, if we conclude that there is a material misstatement therein, we are required to communicate the matter with the Board of Directors and require a correction.

# Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

# Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or related safe-quards applied.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter.

### REPORT ON OTHER LEGAL AND REGULATORY REQUIREMENTS

### **Opinions**

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of BONESUPPORT HOLDING AB (publ) for the year 2020 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated (loss be dealt with) in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

### **BASIS FOR OPINIONS**

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

# Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

# Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Ernst & Young AB, Box 7850, 103 99 Stockholm, was appointed auditor of BONESUPPORT HOLDING AB (publ) by the general meeting of the shareholders on the 19 May 2020 and has been the company's auditor since the 22 April 2010.

Malmö April 13, 2021 Ernst & Young AB

### Ola Larsmon

Authorized Public Accountant

# BONESUPPORT'S SHARE

BONESUPPORT has been listed on Nasdaq Stockholm since 21 June 2017 and from the beginning of 2021 on the Mid Cap segment. The company has ordinary shares (Class A shares) and Class C shares. During 2020, the number of shareholders increased by 3,422 to 5,977 (2,555). The highest share price in 2020 was SEK 78.40 and the lowest was SEK 19.05. The closing price on December 31, 2020 was SEK 77.60.

### **SHARE CAPITAL AND NUMBER OF SHARES**

On December 31, 2020, the share capital amounted to SEK 40,625 thousand divided into 64,999,222 shares with an implied book value per share of SEK 0.625.

### **SHARE TURNOVER**

In 2020, 42,914,799 shares were traded, representing an average turn-over of SEK 8.3 million per trading day.

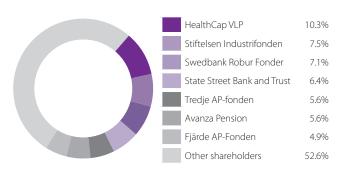
#### **OWNERSHIP**

At the end of 2020, BONESUPPORT had 5,977 (2,555) shareholders, with Swedish shareholders representing 68.25% of capital and 67.70% of votes.

### **DIVIDEND AND DIVIDEND POLICY**

BONESUPPORT has so far not paid any dividends. Any future dividends and the size thereof will be determined on the basis of the company's long term growth, earnings development and capital requirements, taking into account current targets and strategies.

# **SHAREHOLDERS DECEMBER 31 2020**



# **DEVELOPMENT NUMBER OF SHARES 2020**

Date	ate Event	
December 31, 2019	Opening balance	52,521,342
January-December 2020	Conversion of options to shares	660,532
February 2020	Conversion of warrants to shares	250,000
March 2020	Issue of C-shares	730,000
May 2020	Issue of ordinary shares	10,500,000
August 2020	Conversion of warrants to shares	337,348
December 31, 2020	Closing balance	64,999,222

### **BONESUPPORT CLOSING PRICE VS INDEX**



# CORPORATE GOVERNANCE REPORT 2020

BONESUPPORT HOLDING AB (publ) ("BONESUPPORT") is a Swedish public limited company with its registered office in Lund, Sweden. The Company's shares are listed on Nasdaq Stockholm and are traded under the ticker symbol BONEX. BONESUPPORT's corporate governance is based on the applicable statutes, regulations, rules and recommendations for stock-exchange listed companies, such as the Swedish Corporate Governance Code (the "Code"), Nasdaq Stockholm's Rule Book for Issuers, BONESUPPORT's Articles of Incorporation, and company-specific rules and guidelines. For more information, refer to the Company's website www. bonesupport.com. During the 2020 financial year, BONESUPPORT has applied the Code without any deviations.

### **SHAREHOLDERS MEETING**

The Annual General Meeting, or, where applicable, an extraordinary meeting of shareholders, is the ultimate decision-making body of BONESUPPORT, in which all shareholders are entitled to participate. The AGM makes decisions on principle matters, for instance concerning amendments to the Articles of Incorporation, the election of Members of the Board of Directors and the auditor, adoption of the Profit & Loss Statement and Balance Sheet, discharge from liability for Members of the Board of Directors and the Chief Executive Officer, disposition of profits or losses, principles for the appointment of members of the Nomination Committee, and guidelines for remuneration of senior executives.

At the Annual General Meeting on May 19, 2020, 13 shareholders were represented, corresponding to holdings of 50.86 percent of the total number of shares and voting rights in the Company. Advokat Ola Grahn, a lawyer, was elected as Chair of the AGM. At the Annual General Meeting 2020, resolutions were passed on, among other things, the determination of fees for the Board of Directors and the Auditors. re-election of Håkan Björklund, Björn Odlander, Lars Lidgren, Tone Kvåle, Lennart Johansson and Simon Cartmell as ordinary members, authorization for the Board of Directors to resolve on issues, instructions and rules of procedure for the Nomination Committee, adoption of remuneration policy for senior executives, introduction of long term incentive programs for employees and amendment of the Articles of Incorporation. Lennart Johansson was elected Chairman of the Board. Ernst & Young AB were reappointed as auditor with authorized public accountant Ola Larsmon as the auditor in charge.

The Annual General Meeting 2021 will be held on Thursday, May 20, 2021. For further information concerning the Annual General Meeting, please visit BONE-SUPPORT's website. All shareholders have the right to participate and vote for all their shares at the Annual General Meeting. For information concerning shares and voting rights, see the Directors' Report, page 36 in the Annual Report.

# **NOMINATION COMMITTEE**

According to the Swedish Corporate Governance Code, the Company is to have a Nomination Committee, the duties of which shall include the preparation and drafting of proposals regarding the election of Members of the Board, the Chairman of the Board, the Chair at the shareholders meetings and the auditor(s). The Nomination Committee shall also propose directors' fees for Members of the Board and fees for the auditor(s). At the 2020 Annual General Meeting, it was resolved to adopt an Instruction and Rules of Procedure for the Nomination Committee. under which the Nomination Committee is to consist of four members representing the three largest shareholders as per the end of September, together with the Chairman of the Board. For information concerning ownership, see page 73 in the Annual Report or the Company's website www.bonesupport.com.

In accordance with the adopted Instructions, a Nomination Committee has been constituted in preparation of the 2021 Annual General Meeting consisting of Jacob Gunterberg (Chair) representing HealthCap V LP, Bo Lundgren representing Swedbank Robur Fonder, and Jonas Jendi representing Stiftelsen Industrifonden, along with the Chairman of the Board. The composition of the Nomination Committee for the 2021 Annual General Meeting was publicly notified via a press release for the interim report for January - September on November 5th, 2020.

During 2020, the Nomination Committee held two meetings and had ongoing contact between the meetings. The Nomination Committee has complied with the Instructions adopted at the Annual General Meeting on May 19, 2020.

In its work, the Nomination Committee has in its work applied Rule 4.1 of the Code as a diversity policy, whereby the Nomination Committee has taken into account that the Board of Directors, with regard to the Company's business activities, stage of development and circumstances in general, shall be characterized by diversity and breadth with respect to members' qualifications, skills and expertise, experience and background, and that an even gender balance shall be strived for. The Nomination Committee's ambition is that the gender balance will be equalized over time.

### **EXTERNAL AUDIT**

The Company's auditor is appointed by the Annual General Meeting for the period until the end of the next following Annual General Meeting. The auditor examines the Annual Report with accompanying financial statements, as well as the management by the Board of Directors and the Chief Executive Officer. Following each financial year, the auditor shall submit an auditor's report to the Annual General Meeting. Each year, the Company's auditor reports his observations from the audit to the Board of Directors.

At the 2020 Annual General Meeting, Ernst & Young AB was re-appointed as the Company's auditor with authorized public accountant Ola Larsmon as auditor in charge. It was also resolved at the Annual General Meeting that the fees to the auditor should be paid in accordance with the normal billing standards and on receipt of approved invoices. More information regarding the auditor's fees can be found in Note 8 in the Annual Report.

# THE BOARD OF DIRECTORS

After the Annual General Meeting, the Board of Directors is the Company's highest decision-making body. The Board of Directors is responsible for the Company's organization and the management of the Company's affairs, for example by establishing targets and strategies, securing procedures and systems for monitoring the established targets, continuously assessing the Company's financial position and evaluating the operational management. Furthermore, it is the Board of Directors' has the responsibility to ensure that true and correct information is provided to the Company's stakeholders, that the Company complies with laws and regulations, and that the Company develops and implements internal policies and ethical guidelines. The Board of Directors also appoints the Company's CEO and determines his/her salary and other remuneration, based on the guidelines adopted by the Shareholders Meeting.

The Board Members elected by the Annual General Meeting are elected annually at the Annual General Meeting for the term until the next Annual General Meeting is held. Simon Cartmell resigned as a board member by his own request on November 19, 2020. According to the Company's Articles of Incorporation, the Board of Directors is to consist of a minimum of three and a maximum of eight members without alternates. According to the Code, the majority of the Board Members elected by the Annual General Meeting must be independent of the Company and its management. Furthermore, at least two of the Board Members who are

independent in relation to the Company and its management must also be independent in relation to major shareholders. Major shareholders are shareholders who directly or indirectly control 10 percent or more of the total shares and voting rights in the Company. In determining whether or not a Board Member is independent, an overall assessment is to be made of all the circumstances which may call into question the independence of the Board Member vis-à-vis the Company, its management, or the major shareholders. A Member of the Board who is employed or a member of a board of directors of a company that is a major shareholder is not considered to be independent. There are no further provisions in the Articles of Incorporation concerning the appointment and resignation of Members of the Board or amendments to the Articles of Incorporation.

All Board Members elected by the Annual General Meeting, except Björn Odlander, are independent of the major shareholders, and all Board Members elected by the Annual General Meeting, except Simon Cartmell, are independent of the Company and its management. Björn Odlander is independent in relation to the Company and its management, but not in relation to major shareholders as he is a partner of HealthCap. Simon Cartmell is independent in relation to major shareholders, but not in relation to the Company and its management, due to the fact that after the 2018 Annual General Meeting he entered into a consultancy agreement with the Company whereby he regularly assists the Company in matters relating to commercialization strategies, as well as product and business development. As indicated, the Board of Directors is of the view that the Company fulfils the Code's requirement in regard to independence. The Board of Directors' members, own and closely related parties' holdings and the year in which they were elected are presented on the page 73 of the Annual Report.

The Board of Directors follows a written Rules of Procedure, which is reviewed annually and adopted at the statutory Board of Directors meeting. The Rules of Procedure govern, among other things, the Board of Directors' working methods, duties, responsibilities, decision-making within the Company, the Board of Directors' meeting agenda, the duties and responsibilities of the Chairman of the Board, and the allocation of responsibilities and duties between the Board of Directors and the CEO. The Instruction regarding financial reporting and the Instruction to the CEO are also adopted in connection with the statutory Board of Directors meeting.

The work of the Board of Directors is also carried out on the basis of an annual plan, which fulfills the Board of Directors' need for information. In addition to meetings of the Board of Directors, the Chairman of the Board of Directors and the CEO have an ongoing dialogue concerning the management of the Company.

The Board of Directors meets according to a pre-determined annual schedule and shall, in addition to the statutory Board of Directors meeting, hold at least six ordinary Board of Directors meetings between each Annual General Meeting. In addition to these meetings, extraordinary meetings may be arranged to deal with matters that cannot wait until any of the regular meetings. The work of the Board of Directors during the year has followed the framework described above. 16 meetings were held in 2020. See the table below for the attendance record.

Board Member	Meetings
Lennart Johansson	16/16
Håkan Björklund	14/16
Björn Odlander	16/16
Lars Lidgren	16/16
Tone Kvåle	16/16
Simon Cartmell	14/14

The work of the Board of Directors is evaluated annually with the purpose of further developing the Board of Directors' working methods and efficiency. The Chairman of the Board is responsible for the evaluation, and for presenting it to the Nomination Committee. The purpose of the evaluation is to obtain an idea of the Board

Members' views on how the work of the Board of Directors is conducted and what measures could be taken to streamline the work of the Board of Directors, and whether the Board of Directors is well balanced in terms of skills and expertise. The evaluation is an important basis for the Nomination Committee in preparation for the Annual General Meeting.

The Chairman of the Board conducted an evaluation with all Members of the Board in 2020. The results of the evaluation have been reported to and discussed by the Board of Directors and the Nomination Committee.

### Remuneration to the Board of Directors

The directors' fees to be paid to the Members of the Board elected by the Annual General Meeting are decided by the Annual General Meeting. In the preparation of the 2021 Annual General Meeting, the Nomination Committee will make proposals in regard to the directors' fees. At the Annual General Meeting held on May 19, 2020, it was resolved that a directors fee of SEK 325,000 would be paid to the Chairman of the Board and SEK 150,000 would be paid to each of the other Members of the Board who are not employed by the Company. In addition, it was decided that remuneration for work related to the committee is to be paid in the amount of SEK 125,000 to the Chair of the Audit Committee, and SEK 70,000 to each of the other members of the Remuneration Committee, and in the amount of SEK 50,000 to the Chair of the Remuneration Committee and SEK 25,000 to each of the other members of the Remuneration Committee. For the 2020 financial year, remuneration was paid to the members of the Board of Directors as set out in the table below. All amounts are stated in SEK thousands. From April 1, 2020 to September 30, 2020, all board members voluntarily waived 20 percent of their fees.

Name	Task	Remuneration
Lennart Johansson	Chairman of the Board, member of	420
	the Audit Committee, member of the	
	Remuneration Committee	
Håkan Björklund	Member of the Board, Chair of the	200
	Remuneration Committee	
Tone Kvåle	Member of the Board, Chair of the Audit	275
	Committee	
Lars Lidgren	Member of the Board	150
Björn Odlander	Member of the Board, member of the	175
	Remuneration Committee	
Simon Cartmell	Member of the Board	150

### **Audit Committee**

The primary task and responsibility of the Audit Committee is to monitor the Company's financial position, to monitor the effectiveness of the Company's internal controls, internal audit and risk management, to be informed about the audit of the Annual Report and accompanying financial statements/consolidated accounts, and to review and monitor the auditor's impartiality and independence. The Audit Committee shall also assist the Nomination Committee in proposals for decisions concerning the election and remuneration of the auditor. The Audit Committee is comprised of Tone Kvåle (Chair) and Lennart Johansson.

The work of the Audit Committee during the year has followed the framework described above. During the 2020 financial year, the Audit Committee held six meetings and discussed matters concerning the Company's control system, review of quarterly reports, assessment of the auditor's work, and evaluation of risk management. See the table below for the attendance record.

Member	Meetings
Tone Kvåle	7/7
Lennart Johansson	7/7

#### Remuneration Committee

The task and responsibility of the Remuneration Committee are primarily to prepare matters regarding remuneration and other terms of employment for the Chief Executive Officer and members of senior management. The Remuneration Committee shall also monitor and evaluate ongoing and completed programs for variable remuneration of senior executives during the year, and monitor and evaluate the implementation of the guidelines for remuneration to senior executives which the Annual General Meeting has adopted. The Remuneration Committee is comprised of Håkan Björklund (Chair), Björn Odlander and Lennart Johansson.

During the 2020 financial year, the Remuneration Committee held three meetings and dealt with matters regarding the CEO's and other Group management's bonus results for 2019, bonus criteria and salary audit for 2020, plus the implementation of a performance-based share savings program for employees for 2020. See the table below for the attendance record.

Member	Meetings
Håkan Björklund	3/3
Björn Odlander	3/3
Lennart Johansson	3/3

### CEO AND OTHER MEMBERS OF SENIOR MANAGEMENT

The Chief Executive Officer is subordinate to the Board of Directors in the role, the CEO has as the primary task and responsibility to manage the Company's ongoing management and day-to-day business operations of the Company. The Board of Directors' Rules of Procedure and Instruction for the CFO stipulate which matters and issues the Company's Board of Directors is to decide on and which decisions fall. within the area of responsibilities of the CEO. The CEO is also responsible for preparing reports and the requisite basis for decision-making in preparation of the Board of Directors meetings and presents the materials at the Board of Directors meetings.

BONESUPPORT has a management team of nine, including the CEO. For further information about the CEO and other senior executives, please refer to pages 74-75 in the Annual Report.

### Remuneration to senior executives

Remuneration to senior executives consists of a base salary, variable remuneration, pension benefits, share-based incentive programs and other benefits.

Salary and other remuneration for the financial year 2020 were paid to the CEO and other senior executives in accordance with the table below. All amounts are stated in SEK thousands.

	Sc		
		security	Share-based
SEK THOUSAND	Salary	costs	remuneration
CEO	5,700	4,206	1,137
Other senior executives	12,359	4,131	1,155

### Guidelines for remuneration to senior executives

Pursuant to the Swedish Companies Act, the Annual General Meeting shall decide on guidelines for remuneration of the CEO and other senior executives. At the Annual General Meeting on May 19, 2020, guidelines were adopted with primarily the following content:

The Company's starting point is that the Company is to offer remuneration at market levels, and which facilitate the ability to recruit and retain senior executives, and that the terms and conditions must be competitive with consideration of the market practice in the country where the senior executive is employed. Remuneration to senior executives may consist of fixed salary, variable cash remuneration, pension benefits and other benefits.

The base salary shall be determined taking skills and expertise, area of responsibility and performance into account. The variable cash remuneration shall be based on one or more predetermined and measurable criteria that may be financial, such as net sales and operating profit, or non-financial, such as qualitative targets. The variable remuneration shall be capped and for the CEO may not exceed 75% of the annual base salary, and for other senior executives 40% of the annual base salary, whereby the maximum individual level is to be determined based on factors relating to the position held by the specific individual etc.

In addition to what is required by law and collective bargaining agreements or other contracts, the CEO and other senior executives may be entitled to arrange pension solutions on an individual basis. Refraining from receiving a salary and variable remuneration can be used for increased pension contributions, provided that the total cost to the Company is unchanged over time.

In addition, the Annual General Meeting may – and independently of these guidelines - make a resolution regarding, for example, share and share price-related remuneration. The senior executives may be granted other customary benefits, such as a company car, occupational healthcare services, etc.

In the event of termination of a position as a senior executive by the company, the notice period may not exceed twelve months. Severance pay, in addition to salary and other remuneration during the notice period, may not exceed an amount equal to twelve times the monthly salary. In addition, compensation may be paid for any commitment to restrict competition in order to compensate for any loss of income. Such remuneration shall be paid only to the extent that the former senior executive is not entitled to severance pay. The remuneration shall be based on the fixed salary at the time of termination and shall amount to a maximum of 60 percent of the fixed salary at the time of termination, subject to mandatory collective agreement provisions, and shall be paid for the duration of the anti-competition undertakings, which shall not exceed 12 months after termination of employment.

The Board of Directors shall be entitled to deviate from these guidelines in individual cases, if there are special reasons for doing so.

# **INTERNAL CONTROL**

The Board of Directors' responsibility for the internal control is governed by the Swedish Companies Act, the Swedish Annual Reports Act – which requires that information concerning the primary elements of BONESUPPORT's internal control and risk management systems related to the financial reporting each year is to be included in the Corporate Governance Report – as well as the Code. The Board of Directors is to ensure, inter alia, that BONESUPPORT has sufficient internal control and formalized procedures that ensure compliance with established principles for financial reporting and internal control, and that there are effective systems for follow-up and control of the Company's business operations and the risks associated with the Company and its business operations.

The overall purpose of internal control is to ensure, to a reasonable extent, that the Company's operating strategies and targets are monitored and that the shareholders' investment is protected. Furthermore, internal control is to ensure that external financial reporting is, to a reasonable extent, reliable and prepared in accordance with generally accepted accounting principles, compliance with applicable laws and regulations, and that requirements imposed on stock-exchange listed companies are complied with. The internal control primarily consists of the following five components: control environment, risk assessment, control activities, information and communication and monitoring. There is no unit in the Company for internal auditing. The Board of Directors evaluates the need for this unit annually and has made the assessment that, considering the size of the Company, there is not sufficient need to introduce a formal internal audit unit.

#### 1. Control environment

The Board of Directors has overall responsibility for internal control in relation to the financial reporting. In order to establish and maintain a functioning control environment, the Board of Directors has adopted a number of policies and regulatory documents that govern the financial reporting. These consist primarily of the Board of Directors' Rules of Procedure, Instruction for the Chief Executive Officer, and Instruction for financial reporting. BONESUPPORT has also adopted a special authorization policy. In addition, the Company has a financial manual that contains the principles, guidelines and process descriptions for bookkeeping, accounting and financial reporting. The Company has also summarized its procedures for internal control in a separate internal control policy. Finally, the Board of Directors has established an audit committee whose primary task is to monitor the Company's financial position, monitor the effectiveness of the Company's internal control, internal audit and risk management, keep itself informed about the audit of the Annual Report with accompanying financial statements including consolidated financial statements, and review and monitor the auditor's impartiality and independence. The responsibility for the day-to-day work with financial control has been delegated to the Company's CEO, who in turn has delegated this responsibility to the Company's CFO, who has overall responsibility for maintaining sound internal control over the financial reporting environment. The CEO regularly reports to the Board of Directors in accordance with the established instruction for the CEO and the instruction for financial reporting.

### 2. Risk assessment

The risk assessment includes identifying risks that may arise if the basic requirements for financial reporting in the Company are not fulfilled. In a special risk assessment document, BONESUPPORT's management team has identified and evaluated the risks that arise in the Company's business operations and assessed how these risks can be properly managed. Within the Board of Directors, the Audit Committee has primary responsibility for continuously assessing the Company's risk situation, after which the Board of Directors also conducts an annual review of the risk situation. During the year, senior management has reviewed the risks related to strategies, compliance, and financial and operational issues. Afterwards, these risks were assessed according to probability and effect, where risks with either a high degree of probability or potential impact have been prioritized. This has subsequently been presented to the Audit Committee before being reviewed by the Board of Directors. The Company has assigned each risk factor to at least one person in Group management for them to lead the efforts in developing and executing plans for courses of action.

#### 3. Control activities

In order to prevent, detect and correct mistakes and deviations, a framework for control in terms of policies, processes and procedures has been established within BONESUPPORT in relation to control objectives. The control activities help to ensure that the requisite measures are taken to identify and address risks consistent with achieving the Company's objectives. Examples of control activities at an overall level are that BONESUPPORT has a clear governance structure and division of responsibilities with a number of forums and activities which continuously monitor the business operations. Well-defined business processes, separation of duties, and appropriate delegation of authority are also activities that promote good corporate governance and internal control.

Key processes identified to have potential significant risks are mapped out in detail in a separate process description in the financial handbook and key process steps are defined in order to ensure that there is sufficient segregation of responsibilities and that the sufficient control mechanisms are in place.

### 4. Information and communication

BONESUPPORT has information and communication established for the intention to promote the accuracy of financial reporting, and to facilitate reporting and feedback from the business operations to the Board of Directors and senior management, for example by making corporate governance documents such as internal policies, guidelines and Instructions regarding the financial reporting known and accessible to the employees affected. The Board of Directors has also adopted an information policy that regulates the Company's external disclosure.

### 5. Monitoring

The compliance with and effectiveness of the internal controls are continually monitored. The CFO is responsible for ensuring that appropriate processes for monitoring are in place, and the CEO ensures that the Board of Directors continuously receives reports on the developments concerning of the Company's business activities, including the developments with the Company's profits or losses and financial position, as well as information on significant events, such as research results and important contracts. The CEO also makes a report concerning these matters at each Board of Directors meeting. The Company's compliance with relevant policies and guidelines shall be evaluated annually and a report is to be made to the Audit Committee annually by the CFO. A summary of identified proposals for improvements shall then be presented to the Board of Directors.

Lund, April 13, 2021
THE BOARD OF DIRECTORS OF BONESUPPORT HOLDING AB

# AUDITOR'S REPORT ON THE CORPORATE GOVERNANCE STATEMENT

TO THE GENERAL MEETING OF THE SHAREHOLDERS OF BONESUPPORT HOLDING AB (PUBL), CORPORATE IDENTITY NUMBER 556802-2171

# **Engagement and responsibility**

It is the Board of Directors who is responsible for the corporate governance statement for the year 2020 on pages 69-72 and that it has been prepared in accordance with the Annual Accounts Act.

### The scope of the audit

Our examination has been conducted in accordance with FAR's standard RevR 16 The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

# **Opinions**

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the annual accounts and the consolidated accounts and are in accordance with the Annual Accounts Act.

Malmö April 13, 2021 Ernst & Young AB

### Ola Larsmon

Authorized Public Accountant

# THE BOARD OF DIRECTORS



**LENNART JOHANSSON** 

Chairman

Flected: 2017 Born: 1955

Education: MBA from Handelshögskolan, Stockholm

(1980)

Experience: Lennart Johansson has been Senior Advisor for Patricia Industries AB since 2015 and was previously Managing Director (Business Development, Operational and Financial Investments) at Investor AB (2006-2015). Prior to that, he was a partner and CEO of Emerging Technologies ET AB and b-business partners. Today he is a board member of Atlas Antibodies AB, Chalmers Ventures Ab, Hi3G Access AB and Swedish Orphan Biovitrum AB.

Shareholding: 50,000 shares (own holding)



HÅKAN BJÖRKLUND

Member of the Board

Flected: 2016 Born: 1956

Education: Ph.D. in Neuroscience from Karolinska

Experience: Dr. Håkan Björklund is a partner in Tellacq AB, a private investment company. He was elected to the Board of BONESUPPORT in December 2016 in connection with the funding of USD 37 million (SEK 315 million), led by Tellacq. Håkan Björklund has a long and successful career in the healthcare industry, including as CEO of Nycomed. During his time there, Nycomed grew from being a small Scandinavian company to becoming a global business, which was bought by Takeda in 2011. He is currently Chairman of the Board of Swedish Orphan Biovitrum AB.

Shareholding: Owns 25% of the shares in Tellacq AB, which holds 2,361,951 shares.



**LARS LIDGREN** Founder and Member of the Board

Flected: 2010 Born: 1943

Education: M.D., Ph.D. and Professor of Orthopedics

at Lund University

Experience: Doctor of Medicine and Professor of Orthopedics at Lund University Hospital. Lars Lidgren leads a research group in regenerative medicine at Lund University. The unit is a member of the ISOC group, an association of world-leading orthopedic hospitals. He is an honorary member of, and has chaired, several major scientific societies and initiated the global project "Bone and Joint Decade" 2000-2010. Lars Lidgren is a successful entrepreneur, who founded the companies Scandimed (Biomet), AMeC and GWS, Sweden. He is also a board member of the listed companies Orthocell in Australia, Curando Nordic and Safeture in Sweden.

Shareholding: 400,150 shares (own holding and through companies).



BJÖRN ODLANDER Member of the Board

Elected: 2010 **Born:** 1958

**Education:** Medical degree from Karolinska Institutet Experience: Doctor of Medicine in Biochemistry at Karolinska Institutet in Stockholm. Founder and partner of HealthCap. Björn Odlander sits on the boards of Oncorena AB and the KK Foundation, among others.

Shareholding: -



**TONE KVÅLE** Member of the Board

Elected: 2016

**Education:** Diploma in Finance & Administration from UiT Arctic University of Norway, Harstad

Experience: Tone Kvåle has 25 years of experience in the biotech industry. She has been CFO of Herantis Pharma Plc. since October 2020. Prior to Herantis Pharma, she was CFO of Nordic Nanovector ASA, Nor-Diag, Kavli Holding and Dynal Biotech (Norway), and has held senior positions at Invitrogen/Life Technologies, now ThermoFisher (USA). Tone Kvåle has previously been a board member of Badger Explorer ASA.

Shareholding: 15,000 shares (own holding).

# GROUP MANAGEMENT



**EMIL BILLBÄCK**Chief Executive Officer

**Born:** 1970

Employed since: 2018

**Education:** B.Sc. in Business Administration from Karl-

stad University

**Experience:** Emil Billbäck has more than 25 years of experience in life science. His most recent operational role was with BSN medical as Chief Commercial Officer and EVP EMEA. A role as Senior Advisor for ESSITY followed (following SCA's purchase of BSN Medical). Emil lived and worked in the United States for four years and in Germany for ten years.

**Shareholding:** 176,000 shares and 170,000 warrants (own holding).



HÅKAN JOHANSSON

Chief Financial Officer

Born: 1963

Employed since: 2018

**Education:** B.Sc. in Business Administration & Finance

from Mid Sweden University

**Experience:** Håkan Johansson joined BONESUPPORT as Chief Financial Officer in November 2018. He has more than 20 years of experience as CFO and other senior management roles from several industries in the public and private sectors. Prior to BONESUPPORT, Håkan Johansson was CFO for Northern Europe at Thunstall Healthcare Group (2012-2018), a global company in security technology and system solutions for healthcare. He has previously worked at toy manufacturer BRIO AB (publ) and Arctic Paper Group.

Shareholding: 25,000 shares (own holding).



**HELENA L BRANDT**Head of Human Resources

Born: 1965

Employed since: 2017

**Education:** M.Sc. in International Economics from

Lund University

**Experience:** Helena L Brandt has more than 20 years of experience in HR and of managerial positions from a wide range of industries. She has held global HR roles at Astra Zeneca, Sony and Tetra Pak.

Shareholding: 15,000 shares (own holding).



MICHAEL DIEFENBECK

EVP R&D, Medical & Clinical Affairs Chief Medical Officer

**Born:** 1974

Employed since: 2017

**Education:** M.D. from Ludwig-Maximilians-University Munich, Germany. Ph.D. from Friedrich-Schiller-University. Jena. Germany

**Experience:** Michael Diefenbeck is a certified orthopedic and trauma surgeon with 15 years of clinical experience. He founded Scientific Consulting in Orthopedic Surgery in 2014 and has subsequently worked on several projects with BONESUPPORT as an independent medical advisor. He has 16 years of clinical experience from various hospitals in Germany and is the author of 27 published research articles in the field. **Shareholding:** 37,540 shares, 75,000 warrants and 360,000 employee stock options (own holding).



JOHAN OLSSON

EVP Manufacturing & Supply

**Born:** 1965

Employed since: 2007

Education: M.Sc. in Mechanical Engineering from

Lund University of Technology

**Experience:** Johan Olsson has extensive experience from the medical device industry and management experience in production, logistics, purchasing and development. He previously worked as Head of Intensive Care Product Line at Gambro.

**Shareholding:** 3,459 shares and 148,000 employee stock options (own holding).



**ANNELIE AAVA VIKNER** EVP Marketing & Communications

**Born:** 1971

Employed since: 2018

**Education:** Bachelor's degree in Chemistry from Linköping University and further education in leadership from Glasgow Caledonian University

**Experience:** Annelie Aava Vikner joined BONESUP-PORT as Executive Vice President (EVP) Marketing & Communications in March 2019. She has more than 20 years of experience in medical devices and pharmaceuticals. Prior to joining BONESUPPORT, she worked in several leading regional marketing services, within Medtronic, one of the world's leading medical device companies (2002-2019). Her most recent role before BONESUPPORT was as Senior Strategy & Marketing Manager, RTG, ABGI&NORDICS (Restorative Therapy Group, Austria, Switzerland, Benelux, Greece, Israel and the Nordic region).

Shareholding: 15,000 shares (own holding).



**FERGUS MACLEOD** GM & EVP Commercial Operations EUROW

Born: 1970

Employed since: 2019

Education: HND Business & Finance, University of Bedfordshire, Executive Leadership Program, Center for Creative Leadership

**Experience:** Fergus MacLeod joined BONESUPPORT as General Manager & Executive Vice President Commercial Operations EUROW in November 2019. He has more than 20 years experience from international sales leadership positions in the orthobiology and medical equipment sectors with companies such as Johnson Matthey, RTI Surgical and Stryker.

**Shareholding:** 15,000 shares (own holding)



**KRISTINA INGVAR** EVP Quality Management & Regulatory Affairs

Born: 1972

Employed since: 2019

Education: Bachelor of Science in Medicine and Certi-

fied Market Economist

**Experience:** Kristina Ingvar joined BONESUPPORT in February 2020 as Executive Vice President Quality Management & Regulatory Affairs. Kristina Ingvar has a medical degree from Lund University. Prior to BONE-SUPPORT, she worked at Novo Nordisk, where her most recent role has been Global Program Vice President, Regulatory Affairs. During her 20-year career, Kristina Ingvar has had various product, project and person-related responsibilities in regulatory, quality, safety and medical areas. She has worked closely with R&D and manufacturing.

Shareholding: 15,300 shares (own holding)



**MICHAEL ROTH** EVP Commercial Operations for North America

Born: 1963

Employed since: 2020

Education: BA degree in international development

from Clark University

**Experience:** Michael Roth started at BONESUPPORT as General Manager and Executive Vice President Commercial Operations for North America in June 2020. Michael has over 25 years of experience with senior positions in both large and small companies active in orthopedics, with both direct and distributor-led sales. His most recent role was as Vice President of Sales and Marketing for Surgical Planning Associates (HipXpert). He has also served as Vice President of Sales for the Eastern Region at both Wright Medical and Microport Orthopaedics.

Shareholding: 20,533 shares (own holding)

# **GLOSSARY**

**Allograft.** A bone graft transplanted between genetically non-identical individuals of the same species. Allograft can be retrieved from living (taken from the femur head during hip replacement) or from deceased donors.

**Autograft.** A bone graft derived from the patient's own skeleton, usually from the hip bone

**Bone graft substitute.** Synthetic materials used as bone graft instead of biological bone tissue

**Bisphosphonate.** A group of medicines that inhibit bone breakdown

**BMA.** Bone marrow aspirant

BMP. Bone morphogenetic protein

**Class C shares.** Performance shares within the framework of the performance share programs issued in the form of Class C shares

**CERAMENT BVF.** CERAMENT BONE VOID FILLER

**CERAMENT G.** CERAMENT with gentamicin

**CERAMENT V.** CERAMENT with vancomycin

**CERTIFy.** A prospective, randomized, controlled clinical trial of 135 patients at 20 leading trauma centers in Germany, the purpose of which is to compare treatment using CERAMENT BVF with transplantation of autologous bone grafts (autograft)

**CONVICTION.** A randomized controlled trial to evaluate the effectiveness of CERAMENT G in the treatment of chronic osteomyelitis (bone infection).

**CRIOAc.** A healthcare network in France implemented via a nationwide health ministry program to improve outcomes in the management of bone and joint infection.

**DBM.** Demineralized bone matrix. A processed form of allograft, an acid-extracted organic matrix from human bone

FDA. US Food and Drug Administration

**FORTIFY.** A prospective, randomized, multicenter-controlled trial of CERAMENT G evaluating the ability of CERAMENT G to improve treatment outcomes in patients with open tibia fractures

**Haematoma.** A localized build-up of blood outside the blood vessels

**HEOR.** Health Economics and Outcomes Research. Research discipline that quantifies economic and clinical results from medical technology

**Clinical trial.** Trial in humans of, for example, a medical device or a medicine

**LTM.** 12 Months (shows financial outcomes in the last 12 months before end of period)

**Micro-CT.** Microtomography that uses X-ray scanning to recreate a 3D model without damaging the original object

**Osteoinduction.** Osteoinduction means that bone graft material (or growth factor) can stimulate the formation of osteoblasts, which then form new bone tissue

**Osteomyelitis.** A bacterial infection affecting bone tissue

**PMA.** FDA's Market Approval Process for Class III Medical Devices

**The SOLARIO trial.** A randomized unblinded European multicenter trial to investigate whether synthetic bone graft substitute containing antibiotics can lead to shorter treatment times compared to systemic use of antibiotics

**Toxicity.** The degree of damage a substance can cause to humans or animals ("toxicity")

# **DEFINITIONS - ALTERNATIVE** PERFORMANCE MEASURES

BONESUPPORT uses alternative performance measures to increase understanding of the information in the financial statements, both for external analysis, comparison and internal evaluation.

Alternative performance measures are measures that are not defined in financial statements prepared in accordance with IFRS. The following performance measures are used:

# Revenue growth

The difference in net sales between the periods in relation to net sales for the same period of the previous year. Used to measure the business's sales performance.

### **Gross profit**

Net sales reduced by the cost of goods sold. Shows the profit to cover other costs and profit margin.

### **Gross margin**

Net sales reduced by the cost of goods sold, divided by net sales. Shows results in relation to net sales and the margin for covering other costs and profit margin.

### Contribution

Net sales reduced by the cost of goods sold and directly attributable sales costs and research and development costs. Performance measures used to show how a segment performs and its contribution to covering the Group's other costs.

# Interest-bearing liabilities

Borrowings from banks and financial institutions as well as lease liabilities, short and long term. Shows the Group's debt level and forms the basis for interest costs.

### Net debt

Interest-bearing liabilities less cash and cash equivalents. Shows the Group's net lending and is used as a measure to measure the Group's debt/equity ratio and future financing needs.

	2020	2019
Net sales, SEKm	180.9	155.5
Sales growth, %	16.3	60.9
Cost of sales, SEKm	-19.3	-19.6
Gross profit, SEKm	161.6	135.9
Gross margin, %	89.4	87.4
Directly attributable selling expenses, SEKm	-142.0	-159.6
Selling expenses, not directly attributable, SEKm	-13.4	-22.7
Selling expenses including commissions, SEKm	-155.4	-182.3
Directly attributable research & development expenses, SEKm	-23.3	-24.8
Research & development expenses, not directly attributable, SEKm	-34.6	-44.0
Research & development expenses, SEKm	-57.9	-68.9
Contribution, SEKm	-3.7	-48.6

	Dec 31	
SEKm	2020	2019
Non-current borrowings	5.6	5.7
Current borrowings	4.9	4.7
Interest bearing debt	10.5	10.4
Cash and cash equivalents	353.7	92.1
Net debt	-343.3	-81.7

