

# ANNUAL REPORT 2020



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**This annual report is translation of the original Finnish version.**

The market and forward-looking statements and estimates presented in this Annual Report are based on the current views of the Company's management. They contain uncertainty and are subject to changes in the general economic or industry situation.

## YEAR 2020 BRIEFLY

- Clinical test results show that ARTEBONE® paste is yielding an outcome similar to patient's own bone graft in fusions of the ankle and subtalar joints.
- Quality control system and production validation process preparations are in good shape, and the product development process is nearing the end.
- The Company has signed a contract with a Notified Body concerning handling the application and related audits for the CE marking of Artebone. The agreement involved additional documentation requests and further evidence of the functionality of the products . The company commissioned animal experiment and the results of the first and second time point are, according to our interpretation, promising and presumably will fulfil the authority requirements.
- The company received a convertible working capital loan of max. 300 000 euros from Finha Capital Oy, 200 000 euros of this loan were withdrawn.
- The company organised a directed rights issue that raised 5,47 million euros which after deduction of fees and costs amounted to 4,8 million euros. The working capital loan from Finha Capital Oy was converted to company shares.
- The consolidated result for the review period was EUR -2,73 million (EUR -1,69 million in 2019). BBS Plc had no revenue during the financial year 2020
- The Company's cash resources on December 31st 2020, were EUR 3,44 million (EUR 0,52 million in 2019).



## CEO LETTER

The year 2020 was labelled by corona pandemic, which imposed its own challenges, making the operational environment challenging. Despite the circumstances, BBS did well. Our personnel have been working determinately towards company goals and achieved clear results. At the same time the company's internal audits and discussions with the authorities revealed shortages in documentation and production readiness, which is why we communicated about the delays right at the beginning of the year. Despite the factors affecting the schedule, the company has developed its operations and management system to a new level, further strengthening our belief in the company's future.

At the beginning of 2020, we communicated that the clinical test indicated that our product ARTEBONE® Paste is as efficient as the patient's own bone transplant in fusions of the ankle and subtalar joints. This result is so far the most crucial evidence of the operability and shows the market potential of this technology.

During the year the company strengthened its cash position and secured funding to finalise the product development and sales permit application period. First 200 000 euros from Finha Capital Oy as convertible working capital loan and then 5,47 million euros with rights issue directed to Finland and Sweden. This financing is estimated to be sufficient until summer 2022. The funds are planned to be used to finalise the CE marking application process finishing the production

process and validation, USA sales permit process initiation and starting the marketing operations. We see the successful financing rounds as an indication of trust towards what we are building.

Thus, we are well-positioned to take steps towards launching the product to commercial markets. In getting the sales permit, we still have a road to go. In autumn 2020, we signed a contract with a Notified Body concerning handling the application and related audits for CE marking of ARTEBONE®. However, the authority demanded that the complete documentation be submitted as a whole, varying from previous conduct.

The results of the animal test formerly required by the authorities have also been delayed. The results of the first and second time point are already available. As we announced in August, according to our interpretation, the results are very encouraging and presumably will fulfil the authority requirements regarding the sales permit. There were inconsistencies in some of the result interpretations, and for these parts, the testing had to be repeated. We have been forced to wait for the results from the third and last time point longer than anticipated. We expect to have them finalised during spring 2021.

In January 2021, we announced that we expect to receive the CE marking at the end of 2021, assuming that we can submit the application during April. This requires submitting the formerly mentioned documentation as a whole and the result of the third time point.

The company has invested significantly in personnel, strengthening the management of quality operations and capabilities and production personnel. These are essential resources moving from the product development phase to commercial operations. The company has also invested in the development of production and quality control laboratory and the documentation. I have witnessed substantial development in the company and its personnel, and with a solid determination, I believe we will achieve the company's goals.

**IN OULU 31.3.2021**

**ILKKA KANGASNIEMI**

## ARTEBONE® - NEW GENERATION BONE GRAFT

- ARTEBONE contains two main components, which bone comprises of, reindeer bone proteins and mineral scaffold where the bone-forming cell can grow, whereas the majority of competitors' products are mainly based on one main component (TCP).
- Implant's raw material is a natural and ecological product
- When compared with human-based DBM bone-graft substitutes, ARTEBONE® shows no risk of transferring human infectious agents or pathogens.
- ARTEBONE® although including osteopromotive ability, has not shown excess and uncontrollable bone growth nor in preclinical or clinical studies.
- ARTEBONE is priced competitively and offers superior performance compared with single-component products.
- Easy to use and immediately ready to use
- Decreases the total treatment cost due to the reduction of surgical operation's theatre time
- Compared to autografts, decreases the occurrence of complications caused by bone harvesting.



## **Year 2020**

BBS-Bioactive Bone Substitutes Plc (“BBS”, “the Company”) is a biomedical technology Company that develops, manufactures and commercialises innovative, bioactive medical devices and implants for orthopaedic surgery. The Company’s administration and quality control laboratory are in Oulu and production facility in Reisjärvi. The Company has been listed on Nasdaq First North Growth Market marketplaces operated by Helsinki Ltd (BONEH) in Finland and Nasdaq Stockholm in Sweden (BONES).

In early 2020 the Company actions focused on quality system and technical file preparations, process validations as well as finalising the clinical study report. The Company is close to ending of its product development and is approaching its first product launch to the markets. The Company collected new equity from markets to secure the finalisation of its product development and approval of its first commercial product.

To ensure its short-term liquidity the Company decided to take out a working capital loan of EUR 200 thousand in March from Finha Capital Oy, which is one of the Company’s main owners. In June 2020 The Company carried out a share issue in the Nasdaq First North GM marketplace in Helsinki and Stockholm. The issue raised new funds of EUR 5.47 million for the Company. The previously mentioned working capital loan was converted into the Company’s shares in connection with the Rights Issue.

The Company released an announcement in February 2020 about the results of the clinical trial that showed ARTEBONE® Paste to function as well as human autograft in fusion of ankle.

First interim results of the animal trial requested by regulatory authorities were announced on August 31st, 2020. Based on the results, it was concluded that the final report is likely to fulfil the requirements set by the regulatory authorities. Due to inconsistent interpretations of study samples by the study facility an amendment on analytical method was made to study protocol and the measurements were partly repeated.

Management of the Company has estimated that the Company will receive the CE marking for the ARTEBONE® product designed to heal bone fractures and damages during 2021. The schedule described above requires that Notified Body in Europe can process the Company’s CE marking application within eight months of the submission of the application. The Notified Body does not commit to precise application processing times, which means that the Company can only assess the schedule when the CE marking was granted.

The Company objective was earlier to submit the CE marking application to Notified Body in autumn 2020. Then the Company could have received the CE marking in spring 2021. However, in autumn 2020 significant causes of delays were observed.

The US market approval submission to FDA has not advanced significantly during the financial period. Company aims to submit the application to FDA after its application for CE marking has been submitted.

At a general level, the Covid-19 pandemic has caused delays and made the operating environment more difficult. During autumn, the ongoing commissioning of new Medical Device Regulation (MDR) in Europe has highlighted significant number of unfinished documents, quality tests and qualifications of production equipment in the Company. In addition, the Notified Body demands that all documents must be ready for submission at the same time with the CE marking application, whereas according to previous practice, the application could be supplemented during the application process. Furthermore, the further measurements of the animal experiment required by the authority have had to wait longer than expected as the Company released in August 2020. The Company took several corrective actions during end of 2020 to correct the deficiencies due to the above reasons.

To ensure its short-term liquidity the Company decided to take out a working capital loan of EUR 200 thousand in March from Finha Capital Oy, which is one of the Company's main owners. In June 2020 the Company carried out a share issue in the Nasdaq First North GM marketplace in Helsinki and Stockholm. The issue raised new funds of EUR 5.47 million for the Company. The previously mentioned working capital loan was converted into the Company's shares in connection with the Rights Issue.





## **LONG TERM RESEARCH AND DEVELOPMENT**

2020: COVID pandemic caused delays to development work and certification process.

2020: Positive test results from the clinical experiment were published.

2020: Requirements imposed by the new MDR regulation caused additional delays.

2020: An additional animal study to support the application started in 2019 and was completed in 2020. The final results were expected to be available by the end of June 2020. Due to the research institutes inconsistent interpretations, we had to make changes to research plans and have the material analysed again. We are still expecting the final results.

2020: First part of the US patent application was approved.

2020: Investments to product development, production and quality systems that enable commercial production were made after the financing round.

2020: The Company recruited a new quality manager, two new production employees and two new quality control laboratory employees.

2019: FDA certification process was launched.

2019: Quality system ISO 13485 was updated in line with the latest requirements, waiting for certification.

2019: Ilkka Kangasniemi was appointed as the new CEO

2018: CE marking application was submitted to the Notified Body (BSI-UK) in England. Due to the Brexit, the cooperation with them ended.

2016: FDA 510(k) pre-submission package filed

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2015: Production line for reindeer bone protein extract established. License for manufacturing obtained by FIMEA.

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2013 - 2017: All patients operated, and follow-up examinations completed. First approval for clinical trial received in the year 2013 for the patients requiring ankle fusion for posttraumatic osteoarthritis

2009-2012: Patented manufacturing line for clinical trial

2007-2014: Preclinical animal trials for ARTEBONE®. Preclinical animal trials for reindeer bone extract.

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Establishment of BBS-Bioactive Bone Substitutes Company






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Development of the BBS ARTEBONE®. Medical Device Building of small scale manufacturing facilities for preclinical animal trials. R&D Project in Bone Transplantation Research Group of Oulu University.

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Scientific research in the Universities of Tampere and Oulu

## BBS-Bioactive Bone Substitutes Plc's MANAGEMENT

	<p><u>Ilkka Kangasniemi, CEO</u></p> <p>Member of Board since 2019 was appointed as the new CEO since 15<sup>th</sup> October 2019</p>
	<p><u>Hanna Tölli, COO</u></p> <p>In BBS since 2006 COO since August 2020</p>
	<p><u>Merja Haikola, QA Manager</u></p> <p>In BBS since 2006 QA manager and member of the Management Team since August 2020</p>
	<p><u>Soile Hakala, Quality Manager</u></p> <p>In BBS since 2020</p>
	<p><u>Mikko Viitanen, Manager, QC laboratory</u></p> <p>In BBS since 2006</p>
	<p><u>Hannu Säynäjäkangas, CFO</u></p> <p>As CFO from 2015 until 31.1.2021</p>
	<p><u>Liisa Hukka , Talousjohtaja</u></p> <p>CFO from 1.2.2021 In BBS since 1.10.2020</p>

## BOARD of BBS-Bioactive Bone Substitutes Plc.

	<p>Jarmo Halonen, Chairman of the Board of Directors born in 1952, M.Sc. (Eng), in Industrial Mechanical Engineering</p> <p>Member of Board since 2016</p> <p>owns 10 800 (0.21%) of the Company shares</p>
	<p>Pekka Jalovaara born in 1941, MD, PhD, Professor of Orthopedic Surgery</p> <p>Member of Board since 2003 Founder of BBS CEO of BBS 2011-2019</p> <p>owns 532 850 (10.24%) of the Company shares</p>
	<p>Auvo Kaikkonen</p> <p>born in 1960, MD, PhD, Orthopedic and Sports medicine, Orthopedic Surgery MBA</p> <p>Member of Board since March 2017</p>
	<p>Tomi Numminen born in 1971, M.Sc.(Econ.)</p> <p>Member of Board since April 2018</p>
	<p>Seppo Nevalainen s. 1956, M.Sc (Engineering)</p> <p>Member of the Board since August 2020</p>
	<p><u>Ilkka Kangasniemi, CEO</u></p> <p>Member of Board since 2019 was appointed as the new CEO since 15<sup>th</sup> October 2019</p>
	<p>Hannu Säynäjäkangas s. 1954, KTM ja insinööri</p> <p>Talusohtaja BBS-Bioactive Bone Substitutes Oyj 2015-2021</p> <p>Hallituksen jäsen 2012 - elokuu 2020</p>

## FINANCIAL REVIEW

### Key Figures

1 000 €	1.1-31.12.2020	1.1-31.12.2019
Other operating income	46	53
Personnel expenses	795	665
Depreciation and Amortisation	214	225
Other operating expenses	1 599	593
Profit /Loss for the period	-2 731	-1 638
The Cash Flow from Business Operations	-2 418	-1 444
Change in Cash Position	2 923	-1 169
Equity ratio %	48 %	31 %
Earnings per share, EPS €	-0,46	-0,32
Earnings per share €, diluted	-0,45	-0,31
Number of shares at the end of period (BBS)	6 571 525	5 204 820
Average number of shares during the period	5 897 533	5 146 887

1 000 €	31.12.2020	31.12.2019
Cash and cash equivalents	3 438	515
Own capital	6 087	3 079
Balance sheet total	12 692	9 833

\* *Equity Ratio*=

*Equity*  
*(Balance Sheet Total – Advances Received)*

\* *EPS*=

*Profit(Loss)*  
*Average number of Shares during the Period*

## **BBS-Bioactive Bone Substitutes Plc**

<b>FINANCIAL STATEMENTS</b>	<b>1.1.2020 - 31.12.2020</b>
English version (unaudited)	
<b>FINANCIAL YEAR</b>	<b>2020</b>

**BBS-Bioactive Bone Substitutes Plc**

Kiviharjunlenkki 6

90220 Oulu

Domicile Oulu

Business Identity Code

0866451-4

<b>Financial statement for the financial year</b>	<b>1.1.2020 -</b>	<b>31.12.2020</b>
English version (unaudited)		
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The financial statements must be kept for at least ten years after the end of the financial year (Finnish Accounting Act, chapter 2, section 10). Supporting documentation must be kept for a minimum of six years after the end of the year in which the financial year has ended.

## ANNUAL REPORT 1 JANUARY - 31 DECEMBER 2020

### Business Review

BBS-Bioactive Bone Substitutes Plc (“BBS”, “the Company”) is a biomedical technology Company that develops, manufactures and commercialises innovative, bioactive medical devices and implants for orthopedic surgery. The Company’s administration and quality control laboratory are in Oulu and production facility in Reisjärvi. The Company has been listed on Nasdaq First North Growth Market marketplaces operated by Helsinki Ltd (BONEH) in Finland and Nasdaq Stockholm in Sweden (BONES).

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The Company took several corrective actions during end of 2020 to correct the deficiencies due to the above reasons.

## **FINANCIAL REVIEW**

### **Operating result**

BBS Plc had no revenue during the financial year 2020, nor in the corresponding period of the previous year. The consolidated result for the review period was EUR -2,73 million (EUR -1,69 million in 2019 ) consisting of expenses for research and development, administration and finance.

### **Investments and Financing**

The capital expenditure on machinery and equipment at Reisjärvi production site amounted to EUR 82 thousand ( EUR 23 thousand in 2019 ). All the development expenses were recognised as costs in the Profit and Loss statement.

The Company's cash resources at December 31<sup>st</sup> 2020 were EUR 3,44 million (EUR 0,52 million in 2019) and increased by EUR 2,92 million during the period (EUR -1,17 million in 2019)

### **Acquisitions and Share Issues**

There were no mergers or acquisitions during the financial year.

However between June 2<sup>nd</sup> and 18<sup>th</sup> a rights issue was organised both in the Finnish and Swedish market. The Company offered up to 1 301 205 new shares, representing approximately 25% of the company's shares. A total of 1.059.634 shares were subscribed based on pre-emption rights and the remaining 241.571 shares were allocated in accordance with the terms of the placement. Gross assets worth EUR 5,47 million were raised. However shortly afterwards, it became apparent that the subscription and payment of 65 500 shares by an existing shareholder had not been registered properly on the June 24<sup>th</sup> allocation. On June 26<sup>th</sup>, the Board of Directors agreed on an additional private placement of 65.500 shares to the investor at the same price and equal terms as the original issue. Additional EUR 0,27 million was collected.

In total the company received EUR 5,74 million worth gross assets. After the fees, loan conversion and other related costs approximately EUR 4,85 million remained to strengthen the Company's cash position.

Since June 29<sup>th</sup> after the registration of the issue the total amount of the company shares equal to 6 571 525 .

### **Balance sheet**

The balance sheet total at December 31<sup>st</sup> 2020 was EUR 12,69 million (EUR 9,83 million in 2019). At the end of the review period the interest-bearing debts to financial institutions amounted to EUR 6,01 million (EUR 6,33 million in 2019), out of which EUR 0,31 million (0,96) were due in 12 months and EUR 2,14 million (0,88) after five years or later. The long-term interest-bearing debts include a subordinated Capital Loan worth EUR 0,176 million (0,176). The financing costs were EUR -0,085 million (- 102,2 million in 2019)

In March 2020 the Company renegotiated repayment plans for development and working capital loans worth EUR 78 520, 1 844 212, 2 732 000 and 578 680. According to the renewed agreements the repayments are scheduled between June 30<sup>th</sup> 2020 and June 30<sup>th</sup> 2028. The arrangement has a significant impact on reducing the burden of outbound financial cashflow.

During the review period no further development costs were recognised as investments into the balance sheet.

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### **The Capital Loans and Accrued Interest**

The company has a Capital Loan of EUR 175 825,46 pursuant to Chapter 12 of the Limited Liabilities Company Act.

The Loan will be paid back in equal instalments in three years starting in year 2009, if conditions are met. The interest on Loan is one percentage unit lower than the basic interest rate currently in force, however at least three percent. If payment conditions are not met, the interest will be postponed for payment to the first annual closing meeting the conditions.

Accrued interest not recognised as expense is EUR 85 802,68 at the end of the financial year

### **Equity**

The Company's equity at December 31<sup>st</sup> 2020 was EUR 6,09 million. At closing of the financial year December 31<sup>st</sup> .2019 the equity amounted to EUR 3,08 million. During the review period of 2020 a rights issue and an additional private placement were organised strengthening the equity by EUR 5,74 million. The losses of the financial year were EUR -2,73 million.

### **Staff, management and administration**

At the end of the financial period 2020 the company employed the Managing Director and 16 staff members (12 in 2019) . Five new professionals were recruited. The biomedical quality management resources as well as operational production and development resources were strengthened. Eight members of the staff work in the Reisjärvi production site and another eight are placed in Oulu,

Chairman of the Board Jarmo Halonen, Mr.Pekka Jalovaara and Mr.Tomi Numminen belonged to the BBS Board of Directors for the whole review period. Mr Auvo Kaikkonen, Company's CFO Hannu Säynäjäkangas and the Managing Director Ilkka Kangasniemi left their seats at the Annual Shareholders Meeting on August 17<sup>th</sup> as Mr.Seppo Nevalainen was appointed as a new member. After the changes there are two independent members in the BBS Board.

The BBS Management consisted of the Managing Director Ilkka Kangasniemi, CFO Hannu

Säynäjäkangas and COO Hanna Tölli The Quality and Assurance Manager Soile Hakala was invited to the Management Team on August 17<sup>th</sup> .

Ernst&Young Oy, Authorised Public Accountants, acted as the auditor of the company having Mr Jari Karppinen (Auditor certified by the Central Chamber of Commerce) as the auditor with principal responsibility.

### **2019 Annual General Meeting (AGM)**

BBS's AGM was held on August 17<sup>th</sup> 2020 in Oulu. The AGM approved the financial statements for the financial year 2019 and discharged the members of the board of directors and the CEO from liability. The AGM decided in accordance with the proposal by the Board of Directors, that no dividend is paid for the financial year January 1st 2019 - 31 December 2019, and that the loss for the financial year is recognised in the profit/loss account. The AGM decided that the Board of Directors shall comprise of four(4) members. The AGM approved the remuneration of the Board of Directors as follows: The Chairman will be paid EUR 750 per meeting and the other members EUR 500 each. No compensation on e-meetings will be paid. Additionally the Company will compensate reasonable travel expenses according to the Company's travel policy. Ernst&Young Oy, Authorised Public Accountants, was re-elected as the auditor of the Company having Mr Jari Karppinen (Auditor certified by the Central Chamber of Commerce) as the auditor with principal responsibility.

The Annual General Meeting authorised the Board of Directors on the issuance of up to 1 000 000 (one million) new shares, not excluding the right of the Board of Directors to decide on a directed share issue. The authorisation is in force until the next AGM, however no longer than until the 30<sup>th</sup> June 2021.

### **Share-based incentive plan**

The company has a valid option program approved by the AGM on July 18th 2012. The Board of Directors decided on options on January 2<sup>nd</sup> 2013 as authorized by the AGM. Last options were allocated to the key personnel in 2013. Each option entitles its holder to subscribe for one share at the price of one euro., On January 9<sup>th</sup> 2018 the Board of Directors extended the subscription period until December 31<sup>st</sup> 2023. As the number of new shares in the option program is limited to 170 000 representing only three percent (3%) of the total, this has no perceptible impact on the earnings or other key figures per share

### **Valid Authorisations by AGM**

The Annual General Meeting authorised the Board of Directors on the issuance of up to 1 000 000 (one million) new shares The total number of authorisations represent to approximately 15% of the company's share capital, The share issue may be carried out by increasing the share capital by a new subscription or by taking out convertible bonds in one or more tranches. The right to a directed share issue is not restricted. The authorisation includes the right to deviate from the shareholders' pre-emptive right under the Companies Act to subscribe for new shares or convertible bonds, as well as the right to decide on subscription prices, those entitled to subscribe and subscription terms. The share subscription price will be recorded in the invested unrestricted equity fund. The authorisation may be used against the shareholders pre-emptive rights if there is a compelling financial reason for the company, such as the expansion of the company's shareholder base or other arrangement related to the development of the company's business, an incentive program or arrangements in the capital management. Pursuant to the authorisation, shares may also be offered to members of the company's related parties, but not for the benefit of the related parties, deviating from the shareholders' pre-emptive subscription right. The Board of Directors has the right to decide that the shares may be given as subscription in kind, using the right of set off, or other specific conditions.

The authorisation is in force until the next Annual General Meeting, however no longer than until the 30th June 2021.

## **Risks and uncertainties**

Significant risks and uncertainties independent of the Company are identified both in the area of the product development and the commercialising activities. Risks can lead to further postponement, as the authorities have the right to require complements and alterations to the documentation presented. The risk in the product classification lies in the interpretation of the authorities. The decision will be based on the results of the animal testing, which are expected to be available shortly.

The FDA registration process has been started. The matters causing delays in the CE application process may also reflect the FDA registration. In the US, there is a fundamental risk in the 510 (k) approval route that allows the use of precedents. But according to the company's current knowledge, no difficulties are expected in these areas.

Operational risks include, among other things, the dependence on the skills of the key personnel and the measures to strengthen their commitment.

On the financial side, the uncertainty in the stock market caused by the Covid19 pandemic is considered a risk. However, as a medical device development and manufacturing company, BBS is more of a long-term investment. The initial R&D phase takes a long time, followed by four to five years of post-launch marketing and growth of sales. Once sales have become profitable, the growth phase with the same product potentially continues for a long period of time.

## **Shares and shareholders**

The market value of BBS at the end of December 2020 was EUR 31,3 million. The closing valuation on December 31<sup>st</sup> was EUR 4,76. The highest price during the review period was EUR 9,68 and the lowest EUR 1,92.

On December 31<sup>st</sup> 2020, BBS had 3 391 registered shareholders (1 097 in 2019). All the shares are of the same series. There were and 6 571 525 registered shares (2019: 5 204 820) on December 31<sup>st</sup> 2020. Each share is entitled to one vote. The Company's Board of Directors and the Managing Director as persons and through entities under their control had a total of 576 219 (543 650) shares representing 8,8% of the total shares .

170 000 options have been allocated to key personnel, each option entitles to subscribe for one share.

The largest shareholders on December 31<sup>st</sup> 2020 were :

- Finha Capital (1 060.938 s.),
- Reisjärvi municipality (700 721 s.),
- Pekka Jalovaara (550 700 s.),
- EAKR-aloitusrahassto Oy (380 842 s.),
- Irma Halonen (369 276 s.),
- Paananen Ahti (333 379 s.),
- Panvest Oy (305 177 s.),
- Halonen Jukka (184 013 s.),

Nordea Bank Hallintarekisteri (161 198 s.)  
and Innovestor Kasvu-rahasto I Ky (155 326 s.).

Information on the company's insider trading in the company's shares is published on the company's website. The company does not hold any of its own shares.

More detailed information on share issue is available on the Company's website.

### **The Consolidated Companies and Other Closely Related Parties**

BBS Plc owns 100% of the shares of the subsidiary Bio Bones Ltd. Bio Bones Ltd owns and manages the Company's property in Reisjärvi. Bio Bones Ltd had no other business. BBS had no shares in any other companies at the end of the review period.

The related parties of the Company include the members of the Board of Directors and their related parties, as well as the Company's management key personnel and their close associates. In the financial year 2020, there were no related party transactions.

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### **Events after the balance sheet date**

January 11th 2021 the Company announced a new timetable for the CE-marking process, reasons for it and actions taken.

The CFO Hannu Säynäjäkangas retired on February 2<sup>nd</sup> 2021. At the same occasion Ms Liisa Hukka was appointed as the new CFO and a member of the Management Team. The Quality Control Manager Mikko Viitanen was appointed to the Management Team on February 1<sup>st</sup> 2021.

### **Outlook for 2021**

Company's target for the current year is to receive the CE-marking approval. The current management has estimated a new timeline for the process. Currently the Company is aiming to submit the application for review during April 2021. Based on the expected length of review, the CE – marking approval may be expected by the end of the year 2021, which is nine months later than expected earlier.

The preparation for commercial activities will be started in autumn 2021. .

The Board of Directors has launched a detailed cash flow model reaching out for the next 24 months. The model includes presumptions that are based on the current expectations of the future development. Based on the model, the Board of Directors estimates adequacy of the cash resources from the point of business continuity and proactive planning the terms and measures. Based on the information available, the cash resources are expected to suffice until summer 2022.

Currency unit EURO	1.1.2020 - 31.12.2020	1.1.2019 - 31.12.2019
<b>NET TURNOVER</b>	0,00	0,00
Other operating income	45 634,39	52 775,85
Raw materials and services		
Raw materials and consumables		
Purchases during the financial year	-83 061,22	-11 047,22
External services	0,00	-94 641,70
Raw materials and services total	-83 061,22	-105 688,92
Personnel expenses		
Wages, salaries and bonuses	-675 231,30	-568 867,89
Social security expenses		
Pension expenses	-90 529,05	-83 042,60
Other personnel expenses	-29 058,87	-13 101,44
Personnel expenses total	-794 819,22	-665 011,93
Depreciation, amortisation and impairment losses		
Planned depreciation and amortisation	-213 994,51	-225 417,46
Planned depreciation and amortisation total	-213 994,51	-225 417,46
Other operating charges	-1 598 825,86	-592 597,71
<b>OPERATING PROFIT (LOSS)</b>	<b>-2 645 066,42</b>	<b>-1 535 940,17</b>
Financial income and expenses		
Other interest and financial income		
From others	2,27	0,27
Interest and other financial expenses		
For others	-85 916,65	-102 210,21
Financial income and expenses total	-85 914,38	-102 209,94
<b>PROFIT (LOSS) BEFORE EXTRAORDINARY ITEMS</b>	<b>-2 730 980,80</b>	<b>-1 638 150,11</b>
<b>PROFIT (LOSS) FOR THE FINANCIAL YEAR</b>	<b>-2 730 980,80</b>	<b>-1 638 150,11</b>

Currency unit EURO	31.12.2020	31.12.2019
<b>ASSETS</b>		
<b>NON-CURRENT ASSETS</b>		
Intangible assets		
Development expenses	7 532 827,55	7 532 827,55
Other capitalised long-term expenses	307 932,62	359 254,72
Intangible assets total	7 840 760,17	7 892 082,27
Tangible assets		
Land and waters		
Own	83 719,00	83 719,00
Buildings		
Own	479 432,89	515 519,24
Machinery and equipment	640 185,50	684 977,83
Tangible assets total	1 203 337,39	1 284 216,07
<b>NON-CURRENT ASSETS TOTAL</b>	<b>9 044 097,56</b>	<b>9 176 298,34</b>
<b>CURRENT ASSETS</b>		
Debtors		
Short-term		
Other debtors	210 433,63	140 881,37
Prepayments and accrued income	53,33	0,00
Debtors total	210 486,96	140 881,37
Cash and cash equivalents	3 438 153,89	515 633,39
<b>CURRENT ASSETS TOTAL</b>	<b>3 648 640,85</b>	<b>656 514,76</b>
<b>ASSETS TOTAL</b>	<b>12 692 738,41</b>	<b>9 832 813,10</b>

Currency unit EURO	31.12.2020	31.12.2019
<b>LIABILITIES</b>		
<b>CAPITAL AND RESERVES</b>		
Share capital		
Share capital	80 000,00	80 000,00
	80 000,00	80 000,00
Share premium account	1 394 956,56	1 394 956,56
Other funds		
Invested unrestricted equity fund	17 377 537,93	11 638 453,75
Other funds total	17 377 537,93	11 638 453,75
Retained earnings (loss)	-10 034 212,61	-8 396 062,50
Profit (loss) for the financial year	-2 730 980,80	-1 638 150,11
<b>CAPITAL AND RESERVES TOTAL</b>	<b>6 087 301,08</b>	<b>3 079 197,70</b>
<b>CREDITORS</b>		
Long-term		
Capital loans	175 825,46	175 825,46
Loans from financial institutions	5 529 499,00	5 191 297,00
Accruals and deferred income	176 200,00	0,00
Long-term loans total	5 881 524,46	5 367 122,46
Short-term		
Loans from financial institutions	306 728,00	961 473,00
Trade creditors	145 118,76	31 879,90
Other creditors	40 719,43	27 293,22
Accruals and deferred income	231 346,68	365 846,82
Short-term total	723 912,87	1 386 492,94
<b>CREDITORS TOTAL</b>	<b>6 605 437,33</b>	<b>6 753 615,40</b>
<b>LIABILITIES TOTAL</b>	<b>12 692 738,41</b>	<b>9 832 813,10</b>



[1000 euros]	2020	2019
<b>Cash flow from business operations</b>		
<i>Profit (loss) before extraordinary items</i>	-2731	-1638
Adjustments		
Scheduled depreciation and amortisation	214	225
Financial income and expenses	86	102
Other adjustments		
<b>Cash flow before changes in working capital</b>	<b>-2431</b>	<b>-1311</b>
Change in working capital		
Changes in short-term non-interest-bearing (+) (-)	-70	-47
Changes in inventory Increase (-)/ Decrease (+)	0	0
Changes in short-term non-interest-bearing loans Increase (+)/Decrease (-)	-9	18
Changes in long-term non-interest-bearing loans Increase (+)/Decrease (-)	176	0
<b>Cash flow from business operations before financial items and taxes</b>	<b>-2333</b>	<b>-1340</b>
Interest paid and other financial expenses from business operations	-85	-104
Interest received and other financial income from business operations	0	0
Cash flow before extraordinary items and taxes	-2418	-1444
<b>Cash flow from business operations (A)</b>	<b>-2418</b>	<b>-1444</b>
<b>Cash flow from investments</b>		
Investments in tangible and intangible goods	-82	-24
Investments in shares in subsidiaries	0	0
Loans granted		
<b>Cash flow from investments (B)</b>	<b>-82</b>	<b>-24</b>
<b>Cash flow from financing</b>		
Share issue	5739	301
Raised long-term loans	0	0
Repayment of long-term loans	-317	-2
Raised short-term loans	0	0
Repayment of short-term loans	0	0
<b>Cash flow from financing (C)</b>	<b>5423</b>	<b>298</b>
<b>Changes in funds (A+B+C) Increase (+)/Decrease (-)</b>	<b>2923</b>	<b>-1169</b>
Funds at the beginning of the financial period	516	1685
Funds at the end of the financial period	3438	516

	1.1.2020	1.1.2019
Currency unit EURO	- 31.12.2020	- 31.12.2019
<b>NET TURNOVER</b>	0,00	0,00
Other operating income	45 634,39	52 775,85
Raw materials and services		
Raw materials, supplies and goods		
Purchases during the financial year	-83 061,22	-11 047,22
External services	0,00	-94 641,70
Raw materials and services total	-83 061,22	-105 688,92
Personnel expenses		
Wages, salaries and bonuses	-675 231,30	-568 867,89
Social security expenses		
Pension expenses	-90 529,05	-83 042,60
Other personnel expenses	-29 058,87	-13 101,44
Personnel expenses total	-794 819,22	-665 011,93
Depreciation, amortisation and impairment losses		
Planned depreciation and amortisation	-175 173,25	-182 968,36
Planned depreciation and amortisation total	-175 173,25	-182 968,36
Other operating expenses	-1 636 160,41	-620 208,22
<b>OPERATING PROFIT (LOSS)</b>	-2 643 579,71	-1 521 101,58
Financial income and expenses		
Other interest and financial income		
From others	2,27	0,25
Interest and other financial expenses		
To others	-62 438,19	-75 876,95
Financial income and expenses total	-62 435,92	-75 876,70
<b>PROFIT (LOSS) BEFORE APPROPRIATIONS AND TAXES</b>	-2 706 015,63	-1 596 978,28
<b>PROFIT (LOSS) FOR FINANCIAL YEAR</b>	-2 706 015,63	-1 596 978,28

Currency unit EURO	31.12.2020	31.12.2019
<b>ASSETS</b>		
<b>NON-CURRENT ASSETS</b>		
Intangible assets		
Development costs	7 532 827,55	7 532 827,55
Other capitalised long-term expenses	307 932,62	359 254,72
Intangible assets total	7 840 760,17	7 892 082,27
 Tangible assets		
Machinery and equipment	631 980,75	674 038,17
Tangible assets total	631 980,75	674 038,17
 Investments		
Shares of group companies	714 499,55	714 499,55
Investments total	714 499,55	714 499,55
 <b>NON-CURRENT ASSETS TOTAL</b>	 <b>9 187 240,47</b>	 <b>9 280 619,99</b>
<b>CURRENT ASSETS</b>		
Debtors		
Short-term		
Receivables from group companies	1 239,62	0,00
Other receivables	210 433,48	140 881,37
Prepayments and accrued income	53,33	0,00
Debtors total	211 726,43	140 881,37
 Cash and cash equivalents	 3 360 812,98	 487 027,18
 <b>CURRENT ASSETS TOTAL</b>	 <b>3 572 539,41</b>	 <b>627 908,55</b>
 <b>TOTAL ASSETS</b>	 <b>12 759 779,88</b>	 <b>9 908 528,54</b>

Currency unit EURO	31.12.2020	31.12.2019
<b>LIABILITIES</b>		
<b>CAPITAL AND RESERVES</b>		
Share capital		
Share capital	80 000,00	80 000,00
	80 000,00	80 000,00
Share premium account	1 394 956,56	1 394 956,56
Other funds		
Invested unrestricted equity fund	17 377 537,93	11 638 453,75
Other funds total	17 377 537,93	11 638 453,75
Retained earnings (loss)	-9 411 105,10	-7 814 126,82
Net profit (loss) for the financial year	-2 706 015,63	-1 596 978,28
<b>CAPITAL AND RESERVES TOTAL</b>	<b>6 735 373,76</b>	<b>3 702 305,21</b>
<b>CREDITORS</b>		
Long-term		
Capital loans	175 825,46	175 825,46
Loans from financial institutions	5 016 231,00	4 613 829,00
Accrued expenses and deferred income	176 200,00	0,00
Long-term total	5 368 256,46	4 789 654,46
Short-term		
Loans from financial institutions	242 528,00	897 273,00
Trade creditors	142 802,02	127 240,45
Other creditors	39 531,99	26 274,19
Accruals and deferred income	231 287,65	365 781,23
Short-term total	656 149,66	1 416 568,87
<b>CREDITORS TOTAL</b>	<b>6 024 406,12</b>	<b>6 206 223,33</b>
<b>LIABILITIES TOTAL</b>	<b>12 759 779,88</b>	<b>9 908 528,54</b>

[1000 euros]	2020	2019
<b>Cash flow from business operations</b>		
Profit (loss) before extraordinary items	-2706	-1597
Adjustments		
Scheduled depreciation and amortisation	175	183
Financial income and expenses	62	76
Other adjustments		
<b>Cash flow before changes in working capital</b>	<b>-2468</b>	<b>-1338</b>
<b>Change in working capital</b>		
Changes in short-term non-interest-bearing (+) (-)	-71	-47
Changes in inventory Increase (-)/ Decrease (+)	0	0
Changes in short-term non-interest-bearing loans Increase (+)/Decrease (-)	-107	12
Changes in long-term non-interest-bearing loans Increase (+)/Decrease (-)	176	0
<b>Cash flow from business operations before financial items and taxes</b>	<b>-2470</b>	<b>-1374</b>
Interest paid and other financial expenses from business operations	-61	-78
Interest received and other financial income from business operations	0	0
Cash flow before extraordinary items and taxes	-2531	-1452
<b>Cash flow from business operations (A)</b>	<b>-2531</b>	<b>-1452</b>
<b>Cash flow from investments</b>		
Investments in tangible and intangible goods	-82	-24
Investments in shares in subsidiaries	0	0
Loans granted		
<b>Cash flow from investments (B)</b>	<b>-82</b>	<b>-24</b>
<b>Cash flow from financing</b>		
Share issue	5739	301
Raised long-term loans	0	0
Repayment of long-term loans	-252	-2
Raised short-term loans	0	0
Repayment of short-term loans	0	0
<b>Cash flow from financing (C)</b>	<b>5487</b>	<b>298</b>
<b>Changes in funds (A+B+C) Increase (+)/Decrease (-)</b>	<b>2874</b>	<b>-1177</b>
Funds at the beginning of the financial period	487	1664
Funds at the end of the financial period	3361	487

## FINANCIAL STATEMENTS 31.12.2020

**NOTES TO THE FINANCIAL STATEMENTS**

The financial statements have been prepared in compliance with the requirements set for small enterprises (Government Decree on the information presented in the financial statements of a small undertaking and micro-undertaking, chapters 2 and 3 ).

**Valuation and accrual principles and methods followed**

The financial statements have been prepared in accordance with the assumption principles and methods of valuation and accrual provided for in Chapter 2, Section 2a of the Accounting Regulation, with the exceptions listed below:

**Parent company's capitalised development costs**

Development costs, including salaries for capitalised projects. Native project product development completion date was Feb 2015, project continued as a clinical project, which was completed in Dec 2017.

Activations have not been depreciated. Depreciation will begin when the sales begins. The estimated depreciation period is 5 years.

Native project	6 369 319,10
Clinical project	1 163 508,45
	<u>7 532 827,55</u>

**Parent company: capitalised long-term expenses**

Other long-term expenses have been capitalised in accordance with the Accounting Act, Chapter 5, Section 11 in 2017. Cleanroom native project is depreciated by 10 years straight-line depreciation. Started in January 2017.

	<b>31.12.2020</b>	<b>31.12.2019</b>
Cleanroom native project	307 932,60	359 254,72

The capitalisation of the Reisjärvi production facilities and additional investments in the process were fully depreciated completed during 2019.

**Parent company's machinery and equipments**

	<b>31.12.2020</b>	<b>31.12.2019</b>
Native project machinery and equipments	520 854,58	607 663,67

**NOTES TO THE INCOME STATEMENT****Comparability**

In 2020 the cost of external development services have been transferred to other operating expenses as in the financial year 2019 these were presented in external services.

**Parent company: grounds for and changes to the planned depreciations and amortisation**

Category	Estimated service life (years)	Depreciation %	Depreciation method
Other tangible assets	10		Straight-lined
Native project machinery and equipments	10		Straight-lined
Machinery and equipment		25 %	Declining balance

**Consolidated: grounds for and changes to the planned depreciations and amortisation**

Category	Estimated service life (years)	Depreciation %	Depreciation method
Other tangible assets	10		Straight-lined
Buildings		7 %	Declining balance
Native project machinery and equipments	10		Straight-lined
Machinery and equipment		25 %	Declining balance

## FINANCIAL STATEMENTS 31.12.2020

## NOTES TO BALANCE SHEET ITEMS

## Receivables from group companies:

Short-term	31.12.2020	31.12.2019
Other concern receivables	1 239,62	0,00
<b>Short-term receivables from group companies in total</b>	<b>1 239,62</b>	<b>0,00</b>
<b>Concern receivables in total</b>	<b>1 239,62</b>	<b>0,00</b>

## NOTES TO BALANCE SHEET LIABILITIES

## Specification of equity

	Parent company 31.12.2020	Parent company 31.12.2019	Consolidated 31.12.2020	Consolidated 31.12.2019
Share capital at the beginning of the financial year	80 000,00	80 000,00	80 000,00	80 000,00
Share capital at the end of the financial year	80 000,00	80 000,00	80 000,00	80 000,00
Share premium account at the beginning of the financial year	1 394 956,56	1 394 956,56	1 394 956,56	1 394 956,56
Share premium account at the end of the financial year	1 394 956,56	1 394 956,56	1 394 956,56	1 394 956,56
Total restricted equity at the end of the financial year	1 474 956,56	1 474 956,56	1 474 956,56	1 474 956,56
Reserve for invested unrestricted equity at the beginning of the financial year	11 638 453,75	11 337 847,26	11 638 453,75	11 337 847,26
Increase	5 739 084,18	300 606,49	5 739 084,18	300 606,49
Reserve for invested unrestricted equity at the end of the financial year	17 377 537,93	11 638 453,75	17 377 537,93	11 638 453,75
Retained earnings/losses at the beginning of the financial year	-7 814 126,82	-8 231 293,58	-8 396 062,50	-8 775 902,31
Retained earnings/losses from the previous financial year	-1 596 978,28	417 166,76	-1 638 150,11	379 839,81
Retained earnings/losses at the end of the financial year	-9 411 105,10	-7 814 126,82	-10 034 212,61	-8 396 062,50
Profit/loss for the financial year	-2 706 015,63	-1 596 978,28	-2 730 980,80	-1 638 150,11
Total unrestricted equity at the end of the financial year	5 260 417,20	2 227 348,65	4 612 344,52	1 604 241,14
Capital loan	175 825,46	175 825,46	175 825,46	175 825,46
Equity, total	6 911 199,22	3 878 130,67	6 263 126,54	3 255 023,16

## Unrestricted equity in compliance with the Finnish Act on Limited Liability Companies chapter 13, section 5.

	31.12.2020	31.12.2019
Retained earnings from the previous financial years	-9 411 105,10	-7 814 126,82
Financial result (profit+/loss-)	+ -2 706 015,63	-1 596 978,28
Reserve for invested unrestricted equity	+ 17 377 537,93	11 638 453,75
Accumulated unaccounted capital loan interest	- -85 802,68	-80 527,92
Activated development costs	- -7 532 827,55	-7 532 827,55
<b>Unrestricted equity, total</b>	<b>= -2 358 213,03</b>	<b>-5 386 006,82</b>

## Liabilities maturing later than five years:

	Parent company 31.12.2020	Parent company 31.12.2019	Consolidated 31.12.2020	Consolidated 31.12.2019
Loans from financial institutions	1 884 292,00	559 937,00	2 140 760,00	880 605,00
	<b>1 884 292,00</b>	<b>559 937,00</b>	<b>2 140 760,00</b>	<b>880 605,00</b>

In early 2020 a change was made to loans from financial institutions. As a result, short-term debt is reduced and debt maturing later than five years increased.

## FINANCIAL STATEMENTS 31.12.2020

**Liabilities to group companies:**

<b>Short-term:</b>	<b>31.12.2020</b>	<b>31.12.2019</b>
Trade creditors, group companies	0,00	100 755,12
<b>Short-term liabilities to group companies</b>	<b>0,00</b>	<b>100 755,12</b>
<b>Group liabilities in total</b>	<b>0,00</b>	<b>100 755,12</b>

**NOTES ON INCOME TAXES****Unrecognized tax liabilities or assets**

The Group has tax loss of approximately EUR 9,6 million, of which a hidden tax claim at the current income tax rate of 20% is approximately EUR 1,9 million.

**PLEGGED ASSETS AND OFF-BALANCE SHEET COMMITMENTS AND ARRANGMENTS**

	<b>Debts</b>	<b>Corporate mortgages</b>	<b>Value of guarantee placed</b>
<b><u>Parent company</u></b>			
Loans from financial institutions	249 890,00	249 890,00	249 890,00
Falling due for payment with in the next 12 months	27 800,00		
<b><u>Consolidated</u></b>			
Loans from financial institutions	827 358,00	749 890,00	749 890,00
Falling due for payment with in the next 12 months	92 000,00		

**PERSONNEL****Parent company:**

The average number of personnel during the financial year was 13.

**Consolidated:**

The average number of personnel during the financial year was 13.

**NOTES TO THE PREPARATION OF THE CONSOLIDATED FINANCIAL STATEMENTS:**

Accounting principles for consolidated financial statements:

The subsidiary is included in the consolidated financial statements. The consolidated financial statements have been prepared as per the acquisition cost method.

The intercompany transactions, receivables and payables have been eliminated.

**Consolidated subsidiary and ownership:**

<b>Company</b>	<b>domicile</b>	<b>ownership %</b>
Bio Bones Oy	Reisjärvi	100,00



**List of accounting records, document types and methods of storage**

Daily ledger		Electronic archives (CD)
General ledger		Electronic archives (CD)
Purchases ledger		Electronic archives (CD)
Payroll accounting		Electronic archives (CD)
Financial statements		Electronic archives (CD)
Balance sheet specifications		Electronic archives (CD)

## Accounting material 1.11.-31.12.2020

	Receipt type	
Bank entries	01,02	Electronic archives (CD)
VAT receipts	99	Electronic archives (CD)
Accruals	90	Electronic archives (CD)
Purchase invoices	22,45,46	Electronic archives (CD)
Memos	09,13,14	Electronic archives (CD)
Payroll slips	50,55,56	Electronic archives (CD)

Appendices		Electronic archives (CD)
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## Accounting material 1.1.-31.10.2020

Bank entries	NO,NO2	as paper documents
VAT receipts	AL	as paper documents
Purchase invoices	OL	as paper documents
Memos	MU	as paper documents
Payroll slips	PL	as paper documents

## **AUDITOR'S REPORT (translation of the Finnish original)**

To the Annual General Meeting of BBS-Bioactive Bones Substitutes Oyj

### **Report on the Audit of Financial Statements**

#### **Opinion**

We have audited the financial statements of BBS-Bioactive Bones Substitutes Oyj (business identity code 0866451-4) for the year ended 31 December, 2020. The financial statements comprise the consolidated balance sheet, income statement, cash flow statement and notes, as well as the parent company's balance sheet, income statement, cash flow statement and notes.

In our opinion, the financial statements give a true and fair view of the group's and the parent company's financial performance and financial position in accordance with the laws and regulations governing the preparation of financial statements in Finland and comply with statutory requirements.

#### **Basis for Opinion**

We conducted our audit in accordance with good auditing practice in Finland. Our responsibilities under good auditing practice are further described in the *Auditor's Responsibilities for the Audit of Financial Statements* section of our report. We are independent of the parent company and of the group companies in accordance with the ethical requirements that are applicable in Finland and are relevant to our audit, and we have fulfilled our other 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 opinion.

#### **Responsibilities of the Board of Directors and the Managing Director for the Financial Statements**

The Board of Directors and the Managing Director are responsible for the preparation of financial statements that give a true and fair view in accordance with the laws and regulations governing the preparation of financial statements in Finland and comply with statutory requirements. 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 financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Board of Directors and the Managing Director are responsible for assessing the parent company's and the group's ability to continue as going concern, disclosing, as applicable, matters relating to going concern and using the going concern basis of accounting. The financial statements are prepared using the going concern basis of accounting unless there is an intention to liquidate the parent company or the group or cease operations, or there is no realistic alternative but to do so.

#### **Auditor's Responsibilities for the Audit of Financial Statements**

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

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

- Identify and assess the risks of material misstatement of the financial statements, 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 opinion. 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 internal control relevant to the 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 parent company's or the group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting and based on the audit evidence obtained, whether a material uncertainty exists

related to events or conditions that may cast significant doubt on the parent company's or 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 financial statements or, if such disclosures are inadequate, to modify our opinion. 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 the parent company or group to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events so that the financial statements give a true and fair view.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

**Other reporting requirements**  
**Other information**

The Board of Directors and the Managing Director are responsible for the other information. The other information comprises the report of the Board of Directors.

Our opinion on the financial statements does not cover the other information.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated. Our responsibility also includes considering whether the report of the Board of Directors has been prepared in accordance with the applicable laws and regulations.

In our opinion, the information in the report of the Board of Directors is consistent with the information in the financial statements and the report of the Board of Directors has been prepared in accordance with the applicable laws and regulations.

If, based on the work we have performed, we conclude that there is a material misstatement of the report of the Board of Directors, we are required to report that fact. We have nothing to report in this regard.

Oulu, 11 March 2021

Ernst & Young Oy  
Authorized Public Accountant Firm



Jari Karppinen  
Authorized Public Accountant

## **Board of Directors guidance for 2021**

The company expects to launch its first product in the EU market and thus to start its turnover. However, due to Covid-19 and the new MDR-regulation there are unusually many added uncertainty factors. Due to the situation turnover during this year is not expected.

The Company's medium-

term objectives have not changed from last year. The Company expects

- to generate significant revenue growth as a result of a two-year marketing period
- to become profitable after four years
- To launch also in the US and many other countries
- To develop new products
- To establish partnership agreements with industry leaders

### **Board of Directors outlook for 2021**

- BBS begins its CE marking submission process in April. The submission process is expected to progress during the year in a manner revealing the likelihood of acceptance and timeline towards the end of the year.
  - Preparation of the FDA approval submission continues. The goal is to conduct an animal test required by the FDA authorities this year.
  - The Company starts to prepare its sales and marketing operations, when the first response from Notified Body has been received.
  - Preparations for recruiting marketing staff will begin
  - Preparations for the Post market clinical follow up study will begin. The research is mandatory under medical device regulations.
  - Building of a network of key clinical opinion leaders is initiated.
- The Company will start preparation of production when the first response from Notified Body has been received.
- New staff recruitment and training will be continued
  - New production test rounds are performed to meet the needs of animal testing and subsequent clinical work as well as optimization of production.
  - The Board of Directors has confirmed the sufficiency of funds for the Company business until summer 2022. The Company will make preparations during the year for a financial arrangement. Such funds are aimed to secure the Company business continuity and initiation of sales.