ANNUAL REPORT 2019

BBS
BIOACTIVE BONE
SUBSTITUTES

Table of contents:

Year 2019 briefly
CEO's review
ARTEBONE®- new generation bone graft
Company's history
BBS-Bioactive Bone Substitutes Plc's team
BBS-Bioactive Bone Substitutes Plc's Board
Financial Review 1.1-31.12.2019
Financial Statement
Attachment
Auditor's report
Signatures
Outlook for 2020

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 2019 IN BRIEF

- Associate Professor Ilkka Kangasniemi was appointed as the new CEO in October 15, 2019. Previous Managing Director, Emeritus professor Pekka Jalovaara continues as an advisor for the company.
- Quality system ISO 13485 was updated in line with the latest requirements.
- Documentation for regulatory handling of CE marking has been updated to reflect new medical device regulation.
- The patent for the manufacture of the protein extract and the final product itself was approved in Canada. An equivalent patent has been in force in Europe and Eurasia for three years.
- Process, end product and quality assurance validations continued. Some yet incomplete validations have no effect on the timetable for the CE marking application process.
- In 2018, an application was submitted to the Notified Body (BSI-UK) in England for the CE marking of ARTEBONE®. Due to the Brexit the cooperation with them ended.
- In the spring of 2019 the submission was suspended due to observed deficiencies in the content of a previously conducted animal experiment. In addition to the GLP formalities, the lack of equivalence between the dose levels of the samples (higher and lower dose in the animal test differed from the dose in the clinical trial) compared to the clinical trial samples, and the lack of adequacy of the control groups with the established regulatory requirements. The authority decision caused the company to carry out an additional animal study to support the application. Samples from the animal test were delivered for histological analysis at the end of the year and first time point results are expected in spring 2020. The rest of results will be available by the end of June 2020.
- The company has begun preparations for the application process with a Dutch Notified Body (BSI-NL).
- BBS had no sales revenue.
- Cash flow from operating activities was EUR -1.444 (-1.701) million.
- BBS's cash and cash equivalents at December 31, 2019 were EUR 0.515 (1.864) million.
- The company carried out a share issue in the Nasdaq First North GM marketplace in Sweden. The issue raised EUR 0.3 million in new assets to strengthen the company's equity ratio and shareholder base in Sweden. The cost of listing during the period was approximately EUR 50 thousand.

CEO'S REVIEW

Year 2019 was operationally challenging for the company. The authorities' requirement to carry out a supplementary animal experiment to amend its CE marking application caused a delay of more than one year in the submission process. However, this does not affect the performance or safety of the product, which can still be said to be at top level.

A share issue in Swedish Nasdaq First North list was carried out bringing company 0.3 M € in assets and 215 new owners. To be able to execute the next issue of shares boosted by positive news, the company saw it necessary to wait for the clinical report completion, the CE-marking submission and completion of the first interim report on animal testing.

Completion and publication of the clinical report released February 19, 2020 significantly strengthened the company's outlook. For the first time, in 2020 the share price exceeded the IPO level.

The company cash assets were supplemented with 200.000 € as a working capital loan granted by Finha Capital Oy, signed in March 17, 2020. The purpose of the loan is to strengthen the company's liquidity. The loan terms and conditions include an option to convert the loan into shares at the next issue.

Despite the prolonged financial situation, at the end of the fiscal year the company has reached a good position in its aim to move to the next stage of its development. With the new animal test results sufficient documentation can be provided to the authorities for decision making.

The goals for 2019 declared a year ago to begin preparation of marketing and sales functions were transferred forward for the same reason as the regulatory submission process. As a result, this year's targets are almost the same as at the beginning of the previous fiscal year: Completing the EU marketing authorization process and submitting the FDA application. Preparations of marketing and sales operations is initiated, when the authorities give their first, positive, response with questions and comments about the application.

The company has also continued evaluation process with major international players, with the aim to open marketing channels, particularly in the USA, but also in other countries, in areas and that are not BBS's neighboring markets. News of the clinical study outcome has been received positively and expectations to reach next level in the evaluation processes are rising.

In Oulu 20th March 2020

ILKKA KANGASNIEMI

ARTEBONE®- new generation bone graft

- ARTEBONE contains two main components, which bone comprices of, reindeer bone proteins and mineral scaffold where bone forming cell can grow, whereas the majority of competitors' products are mainly based on one main component (TCP).
- Implant's raw material is 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.

Submitting an application for marketing authorization for the first product

The company has during 2019 completed almost all of the required documentation changes that were required by Notified Body to amend the marketing authorization application, submitted in 2018, or by the new medical device regulation. The company has planned to initiate a submission process of a new application to Notified Body in March 2020. However, this

schedule will be delayed because the chosen Notified Body (BSI Netherlands) has announced a delay until May 2020, generated by the increased workload for them due to the new medical device regulation.

The regulatory approval process takes place by Notified Body and in addition by the Competent Authority (CA, National Agency for Medicines) for the drug component of the product, by the CA from which Notified Body so requests. Notified Body has 90 days from the filing date to submit questions and comments on the content of the application. The Competent Authority has 110 days to respond. During this processing, the two authorities will decide whether to accept the classification of the product as a medical device and whether the material submitted meets the requirements of the Directives and Standards for such a product. Thus, at the latest after these waiting periods, the company will either receive product approval or be made aware of any deficiencies and repairs required by the authorities.

At the same time, Notified Body audits the company operations and quality system during the spring and summer of 2020 and issues a quality certificate if no objections can be found.

Normally the authorities will always find comments on the small details, that need to be dealt with and accounted for, before final approval can be obtained. A realistic timetable for the CE marking of the product and a quality system certification is thus set for the end of 2020 or early 2021. However, from the first replies we can already learn what kind of comments are involved and thus form a strong sense of the realism of the timetable.

THE MOST IMPORTANT HISTORICAL STEPS OF R&D AND PRODUCTION

	2019	• Ilkka Kangasniemi was appointed as the new CEO • Quality system ISO 13485 was updated in line with the latest requirements, waiting for certification • FDA certification process was launched • An additional animal study to support the application was completed, The rest of results will be available by the end of June 2020
	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
Production and manufacturing certification	2015	• Production line for reindeer bone protein extract established • License for manufacturing obtained by FIMEA
Clinical trial	2013 - 2017	• All patients operated, and follow-up examinations completed • First approval for clinical trial received in year 2013 for the patients requiring ankle fusion for posttraumatic osteoarthritis
Manufacturing for clinical trial	2009 - 2012	• Patented manufacturing line for clinical trial
Pre-clinical development	2007 - 2014	• Preclinical animal trials for ARTEBONE® • Preclinical animal trials for reindeer bone extract
Company founded	2003	• Establishment of BBS-Bioactive Bone Substitutes Company
R&D & prototyping	1997 - 2007	• 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
Academic research and innovation	1980 - 90's	• Scientific research in the Universities of Tampere and Oulu

COMPANY'S TEAM IS COMMITTED

The research and development in the field of medicine requires perseverance and courage to develop new things. We have over 20 years of expertise in this. Our operations are characterized by top expertise, innovativeness and dedicated and committed employees.

BBS-Bioactive Bone Substitutes Plc's MANAGEMENT TEAM

	Ilkka Kangasniemi, CEO • Member of Board since 2019 • was appointed as the new CEO since 15th October 2019
	Hannu Säynäjäkangas, CFO • Member of Board since 2012 • As CFO since 2015
	Hanna Tölli, Production Manager • In BBS since 2006
	Merja Haikola, QA Manager • In BBS since 2006
	Mikko Viitanen, Manager of QC Laboratory • In BBS since 2006
	Kenneth Sandström, Manager of R&D • In BBS since 2007

BOARD of BBS-Bioactive Bone Substitutes Plc.

	born in 1952, M.Sc. (Eng), in Industrial Mechanical Engineering Member of Board since 2016 owns 10 800 (0.21%) of the Company shares
	born in 1941, MD, PhD, Professor of Orthopedic Surgery Member of Board since 2003 Founder of BBS CEO of BBS 2011-2019 owns 532 850 (10.24%) of the Company shares
	born in 1960, MD, PhD, Orthopedic and Sports medicine, Orthopedic Surgery MBA Member of Board since March 2017
	born in 1971, M.Sc.(Econ.) Member of Board since April 2018
	born in 1964, PhD, Docent of Biomaterials Science, University of Turku CEO of BBS-Bioactive Bone Substitutes Oyj 15th October 2019- Member of Board since April 2019
	born in 1954, M.Sc. (Econ), B.Sc. (Eng) CFO BBS-Bioactive Bone Substitutes Oyj 2015- Member of Board since 2012

FINANCIAL REVIEW 1 JANUARY - 31 DECEMBER 2019

Overview

BBS owns 100% of the subsidiary Bio Bones Oy, which owns a production facility in Reisjärvi. Bio Bones has no other business.

Operating income and development costs

BBS had no net sales in the review period or in the corresponding period of the previous year. The result for the fiscal period 2019 is lower than the previous one because Other Revenue includes a decision taken in 2018 from Tekes (State funding agency) not to collect old R&D loans of EUR 2.224 million.

Financing and investment

At December 31, 2009, the company's cash and cash equivalents were EUR 0.515 (1.685) million. The company estimates that the current funding will be sufficient for approximately three months from the date of this release. The commencement of production and sales activities, and thus the income generating capacity of the intangible assets capitalized on the balance sheet, depends on the success of raising additional financing.

The Group's cash flow from operating activities for the period under review was EUR -1.444 (-1.701) million.

Acquisitions and directed issues

No acquisitions were made during the review period.

BBS organized a directed share issue in Sweden, the issue ended on 30 June 2019. In the issue, the company received capital of approximately EUR 0.3 million before the issue costs, which were estimated to be approximately EUR 0.05 million. More detailed information on the listing can be found on the company's website.

Balance

The consolidated balance sheet total at December 31, 2019 was EUR 9.833 (11.156) million. At the end of the reporting period, the company had loans from financial institutions totaling EUR 6.152 (6.155) million at the end of the review period, of which short-term loans EUR 0.961 (0.522) million. Capital loan was EUR 0.176 (0.176) million. Financial income and expenses totaled EUR -0.102 (-0.097) million. No capitalized product development investments have been made in the balance sheet during the review period.

Own capital

Shareholders' equity at December 31, 2017 was EUR 3.079 million. In the financial statements as at December 31, 2018, shareholders' equity was EUR 4.416 million. During the review period 2019, a directed issue was conducted to Sweden, generating gross income of EUR 0.3 million. Result for the financial year was EUR -1.638 million.

Personnel and administration

The number of personnel at the end of December 31, 2019 was 12. During the period under review, the Board of Directors

comprised Jarmo Halonen (Chairman), Auvo Kaikkonen, Tomi Numminen, Ilkka Kangasniemi, Pekka Jalovaara and Hannu Säynäjäkangas. Pekka Jalovaara served as CEO until October 14, 2019 and Ilkka Kangasniemi served as CEO starting on October 15, 2019.

Annual General Meeting 2019

The Annual General Meeting of BBS Corporation was held in Oulu on 5th of April 2019.

The AGM approved the financial statements for 2018 and discharged the members of the Board of Directors and the CEO from liability. The Annual General Meeting decided in accordance with the Board's proposal, that no dividend be distributed for the financial period 1.1.2018-31.12.2018 and that the loss be recognized in the profit / loss account.

The AGM confirmed the remuneration of the Board members at EUR 500 per meeting and the Chairman EUR 750 per meeting.

The Annual General Meeting decided, that the auditor be paid a reasonable fee against invoice approved by the company. Ernst & Young Oy, an auditing firm, was elected as the auditor of BBS.

The Annual General Meeting decided to authorize the Board of Directors to decide on the issue of shares of 1.500.000 (one and half million) which does not exclude the right of the Board of Directors to decide on a directed share issue. The authorization will be valid until the next Annual General Meeting, however, until the 30th June 2020 at the latest.

Share-based incentive plan

The company has a valid stock option plan 2012 approved by the Annual General Meeting on July 18, 2012. The Board of Directors authorized the Annual General Meeting to decide on stock options on 2nd January 2013. Options have been issued to key personnel and each option entitles its holder to subscribe for one share at a price of one EUR by 31 December 2019. On January 9, 2018, the Board of Directors has extended the subscription period until December 31, 2023. The subscriptions of stock options may amount to a maximum of 170000 new shares and have no appreciable effect on earnings per share.

Risks and uncertainties

The company's risks have recently focused on product approval processes and financial operations. On the approval side, the risk is mainly n keeping timelines, due to the ability of the authority to require additions and corrections to the documentation provided. The product classification is subject to regulatory interpretation. The decision-making will depend on the results of the animal experiment which will be available in the near future. On the US side, the 510(k) certification path that allows predicate use carries a principle risk, but the company's current view is that no difficulty is expected in this respect.

On the financial side, the acute risk is the uncertainty in the stock market caused by the Corona virus. So far, the company's share price has not followed the general trend in stock exchanges. This is understandable as BBS is a long-term investment target as a medical device R&D and production company. The development

phase is long, followed by a 4-5 years post-launch marketing and sales growth phase, and finally, once the sales turn profitable, the company will typically continue its profitable growth phase for a long time. The risk of a share issue failure can also be seen as a financial risk. The volatility of the global economic and the falling stock prices may scare investors.

Shares and Shareholders

BBS's market capitalization at the end of the reporting period 31.12.2019 was by 10.4 million euros. The closing price on December 31, 2018 was EUR 2.00. The highest quotation during the review period was EUR 3.75 and the lowest EUR 1.85.

BBS had 1097 registered shareholders at the register of shareholders on December 31, 2019.

As at December 31, 2018, BBS's Board of Directors and CEO owned a total of 543.650 (532.850) shares, including shares held through controlled companies, or 10.4 % of the Company's stock. Information on insider trading in the company's shares is published on the company's website.

Events after the reporting period

February 19, 2020 The company announced the results of clinical trials, more details on the website. Investors saw the news as positive as the company's share price rose sharply.

In early 2020, product and development loans have been restructured. After the arrangement, the share of short-term financial loans will be EUR 0.316 M and the loans maturing in more than five years will be EUR 2.995 M.

In March 17, 2020, the Company decided to take out a working capital loan of EUR 200.000 to ensure its liquidity.

Accounting Policies

The financial statements bulletin has been prepared in accordance with the Finnish Accounting Act and the rules of the First North Marketplace. The figures in the financial statements release are unaudited.

Financial information 2020

Half-year report January-June 2020 made available by 31.8.2020 at 9:00 am.

Oulu, March 20, 2020

BBS-Bioactive Bone Substitutes Plc

Board

FINANCIAL STATEMENTS AND REPORT 2019

Company's audited report of auditors, financial statement with attachments and signatures will be found from the following link:

http://www.bbs-artebone.fi/wp/wp-content/uploads/2020/04/BBS-Annual-Report-and-Balance-Sheet-Book-2019.pdf

OUTLOOOK FOR 2020

BBS begins its CE marking submission process in March.

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 its sales and marketing operation preparation, 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 mandatory research is required by 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 will be recruited and trained
- New production test rounds are performed to meet the needs of animal testing and subsequent clinical work as well as optimization of production.

The company will organize a share issue during 2020 to enable the realization of the above mentioned objectives.

FOR INFORMATION

February 19, 2020 The company announced the results of clinical trials, more details on the website. Investors saw the news as positive as the company's share price rose sharply.

In early 2020, product and development loans have been restructured. After the arrangement, the share of short-term financial loans will be EUR 0.316 M and the loans maturing in more than five years will be EUR 2.995 M.

In March 17, 2020, the Company decided to take out a working capital loan of EUR 200.000 to ensure its liquidity.