

ANNUAL REPORT 1 JANUARY - 31 DECEMBER 2017

Business overview

BBS-Bioactive Bone Substitutes Oyj (“BBS”, “Company”) is a biomedical technology company that develops innovative, bioactive medical devices and implants for orthopaedic surgery.

BBS’s product development

Preparations for the CE mark application were started in April 2017. The final inspection of the plant was performed and approved in May 2017 within the framework of the building permit.

Two reindeer bone protein batches were produced and stored to wait for the validation of the final product. The product development of the final product continued. The filling machine for syringes was designed and ordered. A product syringe was designed for BBS and the injection moulds were ordered. In addition, a new lyophilizer (freeze-dryer) was ordered for the production process. The design of the validation batches for the final product was started and pre-validation batches were produced with model substances. Bone washing and milling was continued as usual. The validation of analysis methods was continued and the regulatory shelf-life monitoring of proteins was started. The common technical documentation that is used in applying for the CE mark, was written and compiled to be sent to the authorities. Regarding the quality system, the move was made to the ISO13485-2016 system and the quality system was expanded and updated. A full day’s GMP training required by law was organised for the entire staff.

The approval process for the CE mark was taken forward. Notified Body BSI used an expert to assess the acceptability of ARTEBONE. Answers have been provided for the expert’s comments and the additional requirements resulting from them. The matter has been discussed in six conference calls, and a meeting that provide guidelines for what still needs to be done was organised in September 2017 in London. Additional analyses concerning histomorphometry were ordered from the BioSiteHisto laboratory, and these were received by the end of the year. At the end of the year, BSI was notified that BBS will submit the application papers for the CE mark in early 2018, and these papers were collected by the end of the year. The clinical trial was completed. The final control visit took place in December 2017. The draft report for the clinical trial was completed in late December.

Financial review

Operating result

BBS had no turnover in 2017 or in the corresponding period of the previous year. The result for the review period was €-4,427M (2016: €-0,678M). The €2,95M depreciation made on the initial costs of the native project recorded in December 2017 on capitalisations affected the result the most. The depreciation is based on the view shared by the Company’s management and TEKES in autumn 2017, according to which a part of the project’s previous product development work was deemed unnecessary with regard to the functionality or income expectations for the Company’s current and definitive product. This was due, among other things, to the fact that a part of the initial work for the project was done to develop a different kind of product, and thus there is no income expectation any more with regard to the written-down work stages. TEKES conditionally approved the Company’s application made in autumn 2017 for an arrangement with creditors re-

lated to written-down project costs on 13 October 2017: see the section on working capital for more details.

Financing and investments

The Company's finances at 31 December 2017 were €32 486 (2016: €104 311). During the financial year, the Company raised EUR 911 820 through private placement and took out a loan for EUR 100 000.

Working capital

The Company's working capital is not sufficient for the planned needs for 2018, unless the Company is able to secure a total of approximately EUR 5 million in equity financing or debt financing to launch its own production and sales activities. The objective is to raise this working capital requirement primarily in the First North Offering, which is due to commence in late January/early February. Up until now, the Company has been in the product development stage, and operating cash flow cannot be generated until it has received the CE mark for its main product, probably in 2018. The CE mark is required for selling the Company's main product. With the Offering, the Company's objective is to raise at least EUR 5 million in gross funds for the Company's working capital requirement. The Company estimates the operating costs are EUR 1.3-1.6 million for the next 12 months. The Company's estimated repayment for the loans during the corresponding period is EUR 0.7 million, and the Company's planned investments in business activities are €0,3M. The sufficiency of the working capital for the needs of the next 12 months requires that the Offering is realised at least at its minimum realisation amount.

The Company's view is that additional payment time can be negotiated for the loan instalments maturing within a year. Tekes has announced that it will largely write off the two oldest loans, the amount of debt is reduced by approx. EUR 2,2 million, and approx. EUR 0,35 million in accrued interest is removed. The condition for the write-off is that the Company is able to raise EUR 5,0 million in cash for the working capital by 31 March 2018. The Tekes arrangement with creditors is not recognised in the 2017 financial statements, because the condition in it was not met.

Balance sheet The balance sheet total at 31 December 2017 was €9,68M. The balance sheet total at the end of the previous review period at 31 December 2016 was €12,80M. The change is mainly the result of the write-off of capitalisations, see the Operating result section for more details. At the end of the review period at 31 December 2017, the short-term interest-bearing debts on the balance sheets stood at €0,71M (2016: €0,93M), long-term interest-bearing debts €6,2M (2016: €6,05M) and subordinated loans EUR 0,95 (2016: €0,95M) million. The financing costs were €81 thousand (2016: €78 thousand). No product development investments have been capitalised in the balance sheet during the review period.

Staff, management and administration

At the end of the 2017 financial period, the staff numbered 12 (2016:13). During the review period, the Board of Directors consisted of Jarmo Halonen, Pekka Jalovaara, Auvo Kaikkonen, Hannu Säynäjäkangas and Päivi Ylä-Kolu, as well as Timo Heikkilä at the beginning of the period. BBS's management team consists of CEO Pekka Jalovaara, Production Manager Hanna Tölli and CFO Hannu Säynäjäkangas.

2017 Annual General Meeting

BBS's 2017 Annual General Meeting was held on 7 March 2017. In accordance with the proposal by the Board of Directors, the Annual General Meeting decided that no dividend is paid for the

financial year 1 January 2017 - 31 December 2017, and that the loss for the financial year is recognised in the profit/loss account.

Extraordinary General Meeting on 27 June 2017

It was decided to change Section 8 of the Articles of Association to the following: The invitation to the Annual General Meeting must be verifiably submitted to the shareholder in writing no earlier than two months and no later than nine (9) days prior to the record date of the Annual General Meeting. It was decided to remove Section 10 Redemption clause from the Articles of Association, It was decided to add a new Section 11 Book-entry system to the Articles of Association. It was decided to include the Company's shares in the book-entry system, and this took place on 1 August 2017.

Extraordinary General Meeting on 17 October 2017

It was decided that Section 1 Company name and domicile of the Articles of Association would be changed to the following: The Company's business name is BBS-Bioactive Bone Substitutes Oyj, BBS-Bioactive Bone Substitutes Abp in Swedish and BBS-Bioactive Bone Substitutes Plc in English. The Company's domicile is Oulu.

It was decided that EUR 52 015,99 is transferred in the accounts from invested unrestricted capital to share capital by means of reserve increase. The new share capital is EUR 80 000. No new shares are issued in the reserve increase.

It was decided to give the Company's Board of Directors authorisation to decide on the issuing of shares, in which the Board of Directors' right to decide on the private placement is not excluded. The share issue may be carried out by increasing the share capital through a new issue, by obtaining convertible bonds or issuing stock options in one or more batches. Under the authorisation, the Board of Directors may offer a maximum of 2 500 000 (two million five hundred thousand) new shares. The authorisation is valid until the next Annual General Meeting, however, at most until 31 June 2018.

Risks and uncertainties

Significant risks and uncertainties independent of the Company, such as actions by authorities, legislative changes and the desire of the market to receive a new product, are associated with product development and commercialisation. It is not certain that the capitalisations and established losses can be utilised. There are uncertainties which may delay obtaining a sales permit regarding the sufficiency of financing and success of the offering.

Shares and shareholders

BBS had 23 shareholders, all shares are of the same series and there were 4 454 001 registered shares (2016: 4 236 901) at the balance sheet date on 31 December 2017. Each share is entitled to one vote. 170 000 stock options have been given to staff, each option entitles to subscribe for one share. One new shareholder, Jukka Kristo (10 000 shares) joined during 2017, the other shareholders remain the same. No shares have been traded, but the number of shares has been increased by 217 100 through private placement. The largest shareholders at 31 December 2017 were Finha Capital (814 229 shares), Reisjärvi municipality (702 182 shares), EAKR-aloitusrhasto Oy (575 000 shares), Pekka Jalovaara (532 850 shares), Paananen Ahti (267 879 shares), Oulun Seudun Hyvinvointirahasto Ky (260 000 shares), Irma Halonen (259 240 shares), Panvest Oy (250 000) and Innovestor Kasvurahasto I Ky (207 800 shares).

Events after the balance sheet date

In January, BBS took out a short-term loan of EUR 249 997 from Finha Capital Oy to ensure liquidity. In January 2018, Tekes decided to postpone the instalment of the loan maturing in June 2018 (€369k) by two years.

The Board of Directors' dividend proposal to the 2018 Annual General Meeting

At the balance sheet date, BBS had no distributable funds, so the Company's Board of Directors proposes that no dividend is distributed for the financial year 1 January - 31 December 2017.

Outlook for 2018

During 2018, the Company's objective is to obtain the CE mark and launch commercial efforts. To secure funding, BBS seeks to be listed on the First North Finland and First North Sweden marketplaces maintained by Nasdaq Helsinki Oy in late January/early February 2018. Staff will be added to the sales organisation as resources allow.

Board of Directors

Notes to the financial statements

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The government Decree on the Information to be Presented in the Financial Statements of Small and Micro-sized Companies (PMA) has been complied with in preparing the financial statements.

The company named Bio Bones Oy is 100% owned by the Company. The business of Bio Bones Oy is the ownership of the production facilities in Reisjärvi. Its unaudited shareholders' equity at 31 December 2017 was EUR 169 890,82 and the loss incurred was EUR 39 146,25. Bio Bones Oy has EUR 641 668,00 in loans from financial institutions. The Company owes the subsidiary EUR 118 918,02 in rental debts. Consolidated financial statements have not been prepared, because they are not required from a small reporting entity.

Notes concerning the income statement

A report on the grounds for depreciation according to plan and its changes Machinery and equipment for development costs procured during native projects I and II have been depreciated over 10 years on a straight-line basis. Depreciation of these ended on 31 December 2016. Machinery and equipment procured during Native projects III and IV are depreciated over 10 years on a straight-line basis. Depreciation was started 1/2017. Other machinery and equipment will be depreciated in accordance with the maximum depreciation percentage permitted by the Business Tax Act (EVL). The clean room native project is depreciated over 10 years on a straight-line basis. Depreciation was started 1/2017. Additional investments into the Reisjärvi production facility /basic renovation costs are depreciated over 5 years on a straight-line basis.

Depreciation according to plan	31 December 2017	31 December 2016
Machinery and equipment	87 188,92	506,43
Other long-term expenses	74 034,40	107 739,23

Notes concerning the balance sheet

Intangible assets

Project expenses with wages capitalised as development costs

	Native project	Clinical project
Opening balance 1 January 2017	10 187 410,07	1 163 508,45
Project's machinery and equipment transfer *	868 090,97	0,00
Impairment write-down **	2 950 000,00	0,00
Balance 31 December 2017	6 369 319,10	1 163 508,45

* The location of the balance sheet item within the fixed assets has been changed during the 2017 financial year in order to provide better information. Consequently, the grouping for the 2016 financial year has been changed to achieve comparability. With these changes, the machinery and equipment that were capitalised in the product development project during the previous years have been moved to tangible assets, and the project-specific balance sheet breakdown of intangible assets has been changed to correspond to the grouping at 31 December 2017.

** An EUR 2,95 million depreciation made on initial costs of the native project was recorded in December 2017. The depreciation is based on the view shared by the Company's management and TEKES in autumn 2017, according to which a part of the project's previous product development work was deemed unnecessary with regard to the functionality or income expectations for the Company's current and definitive product. This was due, among other things, to the fact that a part of the initial work for the project was done to develop a different kind of product, and thus there is no income expectation any more with regard to the written-down work stages. TEKES conditionally approved the Company's application made in autumn 2017 for an arrangement with creditors related to written-down project costs on 13 October 2017: see the section on working capital for more details.

The completion date for the native project's product development was February 2015. The project continued as the Clinical project, which was completed in December 2017. Capitalisations have not been depreciated. Depreciation will start when the sales activities start. The estimated depreciation period is 5 years.

Other long-term expenditure:

	Additional investments into the Reisjärvi production facility	Clean room, Native project
Opening balance 1 January 2017	68 136,88	513 221,08
Depreciation during the financial year	22 712,28	51 322,12
Balance 31 December 2017	45 424,60	461 898,96
Total intangible assets	8 040 151,11	

In addition to other property, a total of EUR 7 612 499,93 in costs for the native project with its device development and clean rooms have been capitalised in the fixed assets, including the project's machinery and equipment, as well as EUR 1 163 508,45 in costs for the clinical project that followed the native project. In addition, EUR 45 424,60 in additional investments into the Reisjärvi production facility and process have been capitalised in the balance sheet.

Subordinated loans

Tekes/State Treasury	950 000,00
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Debts that mature later than five years from the balance sheet date

State Treasury/Tekes 246/07	257 365,00
State Treasury/Tekes 978/10	1 092 800,00
State Treasury/Tekes 363/15	348 600,00

In the beginning of 2018, a modification was obtained for the State Treasury/Tekes loan 160/09. A three-year additional loan period was applied for, and two additional instalment-free years were approved. For this reason, the amount of short-term debt is reduced by EUR 368 843,00, and debts that mature later than five years from the balance sheet date increase by EUR 922 106,01.

Breakdown of shareholders' equity	31.12.2017	31.12.2016
Share capital at the beginning of the financial year	27 984,01	27 984,01
Share capital increase	52 015,99	0,00
Share capital at the end of the financial year	80 000,00	27 984,01
Share premium account	1 394 956,56	1 394 956,56
Total restricted shareholders' equity	1 474 956,56	1 422 940,57
Invested unrestricted equity fund at the beginning of the financial year	6 977 188,75	6 167 188,75
Increase in the invested unrestricted equity fund during the financial year	911 820,00	810 000,00
Deduction in the invested unrestricted equity fund during the financial year	52 015,99	0,00
Invested unrestricted equity fund at the end of the financial year	7 836 992,76	6 977 188,75
Profit or loss brought forward	-3 804 125,06	-3 125 664,52
Profit or loss for the financial year	-4 427 168,52	-678 460,54
<u>Total non-restricted shareholders' equity</u>	<u>-394 300,82</u>	<u>3 173 063,69</u>
Total shareholders' equity	1 080 655,74	4 596 004,26
Subordinated loan Tekes/State Treasury	950 000,00	950 000,00
Shareholders' equity + subordinated loans	2 030 655,74	5 546 004,26

Distributable non-restricted shareholders' equity	
Invested unrestricted equity fund	7 836 992,76
Profit or loss brought forward	-3 804 125,06
Profit or loss for the financial year	-4 427 168,52
Development costs capitalised in the balance sheet	-7 532 827,55
Distributable non-restricted shareholders' equity 31 December 2017	-7 927 128,37

At the balance sheet date, the Company has 4 454 001 registered shares and 170 000 registered stock options. Each share entitles to one vote at the general meeting.

Accrued unpaid interest

Subordinated loan

Tekes/State Treasury 9/3-31/8/2005	3 737,46
Tekes/State Treasury 1/9/2005-31/8/2006	10 674,67
Tekes/State Treasury 1/9/2006-31/8/2007	19 849,37
Tekes/State Treasury 1/9/2007-31/8/2008	32 765,59
Tekes/State Treasury 1/9/2008-31/8/2009	35 625,00
Tekes/State Treasury 1/9/2009-31/8/2010	28 500,00
Tekes/State Treasury 1/9/2010-31/8/2011	28 500,00
Tekes/State Treasury 1/9/2011-31/8/2012	28 500,00
Tekes/State Treasury 1/9/2012-31/12/2013	38 000,00
Tekes/State Treasury 1/1-31/12/2014	28 500,00
Tekes/State Treasury 1/1-31/12/2015	28 500,00
Tekes/State Treasury 1/1-31/12/2016	28 500,00
Tekes/State Treasury 1/1-31/12/2017	28 500,00

Commitments and contingent liabilities in the notes

Debts secured by a business mortgage

Business mortgage 3 * EUR 100 000 = EUR 300 000, relating to Finnvera Oyj's loan, whose amount is EUR 277 690,00.

Notes on members of the institutions and staff

Average number of staff during the financial year

	31.12.2017	31.12.2016
Staff	12	13

Other notes

Financing for development and future production activities is actively pursued. At the balance sheet date, the total investment in different kinds of equity and subordinated loans was EUR 2 030 655,74. The aforementioned subordinated loans include the EUR 950 000,00 subordinated loan granted by TEKES. Both equity and other financing is still being actively procured.

The Company's working capital is not sufficient for the planned needs for the calendar year 2018, unless the Company is able to raise in total approximately EUR 5 million in equity or debt financing to launch its production and sales activities. The objective is to raise this working capital primarily in the First North Offering, which is scheduled to commence in late January/early February 2018.

Up until now, the Company has been in the product development stage and may start to generate a cash flow from operating activities when the Company receives a CE mark for its main product, probably in 2018. The CE mark is required to sell the Company's main product. With the Offering, the Company's objective is to raise at least EUR 5 million in gross funds for the Company's working capital requirement. The Company estimates that the operating costs

for the next 12 months are EUR 1,3-1,6 million. The Company's estimated repayment for the loans during the corresponding period is EUR 0,3 million, and the Company's planned investments in business activities are EUR 0,3 million. The sufficiency of the working capital for the needs of the next 12 months requires that the Offering is realised at least at its minimum realisation amount.

The Company's view is that additional payment time can be negotiated for the loan instalments maturing within a year. Tekes has announced that it will largely write off the two oldest loans, the amount of debt is reduced by approx. EUR 2,2 million, and approx. EUR 0,35 million in accrued interest is removed. The condition for the write-off is that the Company is able to raise EUR 5,0 million in cash for the working capital by 31 March 2018. The TEKES arrangement with creditors is not recognised in the 2017 financial statements, because the condition in it was not met. Company management may influence the investments made and amount of the costs.