



# **INNOVATING FOR HEALTH**

**Biohit Oyj • Financial Statement Release 2016**

## BIOHIT GROUP FINANCIAL STATEMENT RELEASE 2016

Biohit Oyj Financial Statement Release, 20 February 2017 at 9:30 am local time (EET)

### SUMMARY

#### January–December 2016

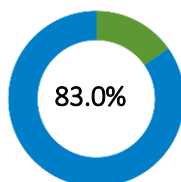
- Net sales grew by 35.4% compared to 1-12/2015
- Net sales EUR 8.2 million (EUR 6.1 million)
- Operating loss, EUR -3.4 million (EUR -2.9 million)
- The result for the reporting period was EUR -3.3 million (EUR -2.9 million)
- Net sales from international operations 92.2% (88.3%) of total net sales
- Equity ratio 83.0% (87.9%)

#### July-December 2016

- Net sales grew by 72.8% compared to 7-12/2015
- Net sales EUR 4.4 million (EUR 2.5 million)
- Operating loss, EUR -1.3 million (EUR -1.4 million)
- The result for the reporting period was EUR -1.2 million (EUR -1.6 million)
- Net sales from international operations 93.7% (88.9%) of total net sales
- Equity ratio 83.0% (87.9%)



Net sales  
grew  
**35.4%**  
compared to  
2014



Equity ratio  
**83.0%**



Net sales from  
international  
operations  
**93.7%**

## PRESIDENT & CEO SEMI KORPELA:

'In the second half of 2016 our net sales grew by 72.8% compared to the comparison period 7-12/2015. During the entire year our net sales grew by 35.4% compared to 1-12/2015. In terms of operational development, Biohit Oyj has focused on supporting the business activities of our joint



venture Biohit HealthCare (Hefei) Co. Ltd, expanding the international distributor network and supporting partners, for example in product registrations. Especially our operations in China developed in a favorable manner in 2016 and our joint venture exceeded EUR 5 million in net sales with GastroPanel® (EUR 0.2 million in 2015) and made a positive operational result (EUR -1.1 million 2015).

Our most important products are GastroPanel®, Acetium and diagnostic quick tests. Our main market areas are Asia and Europe. The smoking intervention study, which started in 2016, burdened the financial year's costs in 2016 but other comparable non-IFRS costs were at a similar level than 2015. For 2017 the costs are not expected to grow, as the cost burden associated with clinical studies focused on the year 2016. In addition the net cash flow from operating activities improved by EUR 0.6 million compared to 2015.'

### **We expanded our distributor network and advanced product registrations**

We continued expanding our distributor network with new agreements and by restructuring agreements. During 2016 we signed following distribution agreements of Biohit's diagnostic products: OnSite Diagnostic Lab India Pvt Ltd sells our diagnostic tests in India and SPD Scientific Pte Ltd. in Thailand. In the Philippines UC Biosciencies Inc. will distribute diagnostic tests. Pooyandegan Pezeshki Pardis was appointed as the GastroPanel® distributor in Iran and Delta Biologicals S.r.l in southeast Italy. Tianjin Jingsheng Biological Technology Development Co. Ltd was appointed as distributor for Biohit's calprotectin-test in China. We renewed the agreement with our Russian partner Melon OOO for the exclusive right to distribute our diagnostic products to a further contract period. In addition, we made a celiac disease quick test and GA-map™ dysbiosis test distribution agreements with Beijing HuayiHuilang Medical Instrument Co.,Ltd in China and Glomedics distributes Lactose Intolerance Quick Tests in South Korea. In Sri Lanka Easemed Global Ltd was appointed as distributor for Helicobacter Pylori Quick Test. Furthermore, an agreement with exclusive right to distribute calprotectin-test in Iran was made with Iranian Arad Tajhiz Azma. In Sweden diagnostic tests are distributed through XboXLab AB.

During the reporting period Ericon S.r.l. in Moldova and Inversiones Naturalia S.A in Panama got exclusive rights to sell Acetium. The acetaldehyde binding L-cysteine capsule, which was registered in Mexico as a food supplement and under a product name Etium, was granted an import license in Mexico in May 2016. The first batch was delivered to Mexico in early summer. During the first half

of 2016 several diagnostic test registrations were concluded in Costa Rica. In the end of 2016 Indian authorities granted import license for Biohit's several diagnostic tests. Additionally, during the second half of 2016 registrations in Thailand for several diagnostic tests, a re-registration of GastroPanel® and H. Pylori quick test in Kazakhstan and registration of ColonView, UFT300 and Quick test reader in Israel were concluded.

During 2016 a price approval decision on the three GastroPanel® tests (pepsinogen I, pepsinogen II, gastrin-17) was issued in four Chinese provinces. The price approval decision has already been issued in 20 provinces. Price approval is a pre-requisite for reimbursability of GastroPanel® and start of sales.

In general, the duration of the product registration process is different in each market area. For this reason, it is not possible to accurately assess the time it takes for the authorities to handle registrations in different countries and for product sales to begin.

#### **We bought a share of Norwegian Genetic Analysis AS with a directed share issue**

Biohit Oyj and Genetic Analysis AS signed a share exchange agreement through which Biohit Oyj acquired ownership of 18% of shares in the company. In addition to this the companies have signed a distribution agreement giving Biohit Oyj a right to sell Genetic Analysis AS's Dysbiosis Test under the Biohit brand and exclusively in Finland and in China. In the future, Genetic Analysis will also operate as a distributor to Biohit Oyj's products and services in Norway.

#### **Biohit Oyj's Chinese joint venture starts production**

Biohit Oyj's Chinese joint venture Biohit HealthCare (Hefei) Co. Ltd production facility has passed official test requirements and has been granted a license enabling production and sales of products. Biohit HealthCare (Hefei) Co. Ltd manufactures GastroPanel®-products developed by Biohit Oyj for the Chinese market.

#### **Screening studies provided additional information about the diagnosis of gastric cancer risks and the frequency of vitamin B12 deficiency**

More research evidence was obtained on the association of *Helicobacter Pylori* with gastric cancer. The long-term follow-up of the subjects who participated in a population-based screening during 1994-1996 was completed and the report was published in Scandinavian Journal of Gastroenterology. The study confirms the previous observations, according to which helicobacter infection alone increases significantly the risk of gastric cancer. This risk increases substantially when an untreated helicobacter infection has progressed to atrophic gastritis.

Furthermore, we obtained additional evidence that GastroPanel® test predicts the risk of stomach cancer. In GastroPanel® test, a low Pepsinogen I level predicts stomach cancer risk even ten years in advance. These results were obtained in two separate studies among Asian and Caucasian

population, where the subjects were followed-up for several years after GastroPanel® testing. The long-term predictive value of GastroPanel® test as a predictor of this risk has not been previously confirmed in a Caucasian population.

According to a study conducted in Estonia and Finland, in the majority of cases in Estonia but less than 25% in Finland, vitamin B12 deficiency remains undiagnosed among elderly people. In that study, the frequency of atrophic gastritis and levels of vitamin B12 were compared among elderly people in both countries.

### **Cancer screening pilots continued in China and Russia**

We continued our efforts towards advanced medical practices, especially in cancer screenings. The two pilot screening trials for gastric cancer risk started in China in 2015 continued, using Biohit Oyj's GastroPanel® test. The first of these is a project of the National Clinical Research Center for Digestive Diseases (Changhai Hospital), funded by the Ministry of Science and Technology of China. The Ministry is the coordinator of this multi-center study screening the risks of early gastric cancer. In the study, at least 20,000 persons will be screened in some 50 hospitals. The screenings were expected to be concluded by the end of 2016.

The second study is being conducted in Chinese healthcare centers by the China Health Promotion Foundation. The foundation is a public organisation, administered by the Chinese Ministry of Health. Around half a million 40-80-year-old asymptomatic subjects will be screened in this trial. The sample collection has started in the summer of 2015 and continued over the whole year 2016. Due to the fact, that both organisational sides of the study are public organisations, and independent of Biohit Oyj and its joint venture, there is no specific information available about the exact time of completion.

In 2015, Russian Federation started a pilot project for colorectal cancer screening, targeted to 48-75-year old asymptomatic persons. In the pilot project, around 20,000 persons will be screened, and the results are expected to be available during 2017. Based on these results, the final selection of the screening test to be used in the national screening program will be made, and one of the options is Biohit Oyj's ColonViewFIT test. The national screening is organised and sponsored by the Russian Federal Government and it will be conducted by local medical centers.

### **We brought our expertise for food industry**

In 2016 we started a cooperation with Pyynikin Craft Brewery and brought our biotechnological expertise at the disposal of the brewery production process. As a result of this cooperation, Pyynikin Craft Brewery launched a new beer brand called Pyynikin Vapaa (Pyynikki's Free), responding to the consumers' demands. The product is, among other properties, a gluten-free product and it has a very low acetaldehyde level. The cooperation with the brewery is a new business area for Biohit and it paves the way for developing the production of other food stuffs as



well. We want to be part of the development aimed to offering the customers alimentary products made of pure raw materials.

## THE GROUP'S KEY FIGURES

	7-12/2016	7-12/2015	1-12/2016	1-12/2015
Net sales (MEUR)	4.4	2.5	8.2	6.1
Operating profit/loss (MEUR)	-1.3	-1.4	-3.4	-2.9
Profit/loss before taxes (MEUR)	-1.2	-1.6	-3.3	-2.9
Profit/loss for the period. total (MEUR)	-1.2	-1.6	-3.3	-2.9
Average number of personnel	52	51	53	52
Number of personnel at the end of the period	49	49	49	49
Equity ratio (%)	83.0%	87.9%	83.0%	87.9%
Earnings per share (EUR)	-0.08	-0.11	-0.22	-0.20
Shareholders' equity per share (EUR)	0.73	0.72	0.73	0.72
Average number of shares during the period	14 698 533	14 347 512	14 685 071	14 276 519
Number of shares at the end of the period	14 698 533	14 348 533	14 698 533	14 348 533

## REPORTING

Biohit's product portfolio consists of diagnostic tests, analysis systems, products binding carcinogenic acetaldehyde into a harmless compound, monoclonal antibodies and service laboratory operations. The entire product and service portfolio is reported under a single segment.

## NET SALES AND RESULT

### January-December

Net sales grew by 35.4% compared with 1-12/2015.

The operating loss was EUR -3.4 million (EUR -2.9 million 1-12/2015). The result during the reporting period totalled EUR -3.3 million (EUR -2.9 million).

### Consolidated net sales and operating profit

	7-12/2016	7-12/2015	Change	1-12/2016	1-12/2015	Change
Net sales MEUR	4.4	2.5	1.8	8.2	6.1	2.1
Change compared with the previous year (%)	72.8%			35.4%		
Operating income MEUR	-1.3	-1.4	0.2	-3.4	-2.9	-0.5
Change compared with the previous year (%)	10.8%			-15.7%		
Operating income (% of net sales)	-29%	-57%		-41%	-48%	

## BALANCE SHEET

On 31 December 2016, the balance sheet total was EUR 13.0 million (EUR 11.7 million). Biohit's balance sheet provides the necessary foundation for building new business and for utilising the significant potential of the company's products. At the end of 2016, our equity ratio was 83.0% (87.9%).

## FINANCING AND OPERATIONAL CONTINUITY

Biohit Oyj has a moderate financial position, which allows for the necessary actions towards creating an international distributor network as well as the development and commercialisation of new products. Liquidity is at a good level. At the end of the reporting period, the company's financial assets totalled EUR 7.7 million (EUR 7.2 million) containing EUR 3.2 million worth of Genetic Analysis AS shares.

Despite loss making financial periods the company has managed to keep its working capital on a good level and the management believes the working capital will cover the operations for the next 12 months and the company is not dependent on external financing to be able to guarantee the continuity of its operations. Furthermore, as announced on 2 January 2017, the company expects to receive EUR 1.8 million cash during the first half of the year from the ownership arrangement of its joint venture, which is expected to strengthen company's working capital structure. The transaction requires approval from the authorities. Company's management assessment is that company's ability to continue its operations is good and there are no indications towards events or

circumstances that alone or together might give a significant reason to doubt the organisation's ability to continue its operations.

## RESEARCH AND DEVELOPMENT

R&D operations focus on innovations, as well as product development and improved usability. Biohit also employs external experts and subcontractors in its R&D operations. Development expenditure has not been capitalised. Research and development expenditure during the 1-12/2016 reporting period amounted to EUR 2.0 million (EUR 2.0 million), of which the second half-year accounted for EUR 0.8 million (EUR 1.0 million).

The main focus was in the development of the GastroPanel® quick test. The quick test is particularly suitable for the test assortment at doctor's offices and small laboratories, and it is designed to operate with an automatic reader. During 2016, a dysbiosis test was launched on the market measuring the gut microbiota. A bone density measurement (by a newly designed equipment) was added to the test portfolio of our laboratory services.

## CLINICAL RESEARCH

### **Ongoing clinical trials continued and new trials were started**

To confirm the promising results of the smoking intervention study, which was concluded in November, 2015, a new, more comprehensive study with Acetium lozenge was designed. The study setting is similar as in the previous study, in which Acetium lozenge was found to be more effective than placebo in assisting the cessation of smoking. This needs to be confirmed in an adequately powered study. The new study with larger series of patients started in spring 2016 and continues until the first half of 2017. L-cysteine slowly released from Acetium lozenge binds the human carcinogen acetaldehyde in the saliva to form a harmless compound, and in addition, improves oral health.

An international study comparing colorectal cancer screening tests still continues in Barretos, Brazil. It has a similar design as the study completed in 2015 but the cohort of screened patients is larger. This study is close to completion and compares the sensitivity and specificity of Biohit Oyj's ColonViewFIT test and a traditional guaiac-based method as a screening test for colorectal cancer. Based on the interim results, an abstract was submitted for the 2017 congress of DDW (Digestive Disease Week) in the USA.

During 2016, the two randomised double-blind trials on patients who suffer from migraine and cluster headaches still continued. Due to the slow recruitment of the patients, the progress of these two studies is delayed. There are no interim results available.



Year 2016 was also the starting point for a long-term treatment trial in two clinics in Italy, where the efficacy of Acetium capsule in the treatment of atrophic gastritis or in intervention of disease progression is tested in a randomised placebo-controlled trial. This study setting necessitates a sufficient number of patients who fulfill the selection criteria and an adequate follow-up period after therapy. Due to these reasons, the total duration of the project will be at least three years.

The results of the senior citizens study, which was concluded at the end of 2015, were published during 2016 in the Journal of Aging Research and Clinical Practice. In this study, more than 200 residents of assisted housing facilities in Finland (Tampere) and Estonia (Tartu), with an average age of over 80 years, were tested with GastroPanel®- and vitamin B12 measurement. The aim was to compare the prevalence of atrophic gastritis, helicobacter-infection and B12 vitamin deficiency. The study disclosed significant differences in the general health of these elderly people between the two countries. This applies particularly to the prevalence, detection rate and management practices of helicobacter infection and vitamin B12 deficiency. Atrophic gastritis detected by GastroPanel® examination is a common cause of vitamin B12 malabsorption, an early diagnosis of which is emphasised also in this study.

### **Novel results on the use of GastroPanel® test and a meta-analysis**

In 2016, Biohit's Department of Clinical Research made a systematic review of the entire literature published on the use of GastroPanel® test in diagnosis of atrophic gastritis worldwide. All studies fulfilling the inclusion criteria were subjected to a formal meta-analysis. Meta-analysis is a statistical technique, which is suitable for calculating the pooled sensitivity and specificity of GastroPanel® test in diagnosis of atrophic gastritis, based on all published studies. Altogether, 27 studies fulfilled the inclusion criteria, comprising nearly 9000 patients tested with GastroPanel® in different countries and continents. Despite substantial variation between individual studies, the pooled results of this meta-analysis are encouraging and clearly substantiate the positive experiences of this test, reported in Biohit's own studies and in those conducted by its partners. Especially important is the high specificity of GastroPanel® test in detecting atrophic gastritis signifying in practical terms that in cases with a completely normal test result a probability of atrophic gastritis or helicobacter-infection in the stomach is negligible.

In addition to this meta-analysis, also two other studies with significant results conducted by Biohit or its partners were reported in Anticancer Research-journal during 2016. One of these is a screening study with GastroPanel® conducted in St. Petersburg with asymptomatic patients and the other one is a case-control study with 10-year longitudinal setting, in which the value of GastroPanel® as a predictor of a long-term risk of gastric cancer was estimated. The suitability of GastroPanel® as a screening tool of asymptomatic population was excellent and the test was sensitive and specific to detect a. o. atrophic gastritis ([www.biohithealthcare.com/additional-information](http://www.biohithealthcare.com/additional-information)). In the case-control study, the below-threshold levels of GastroPanel® markers (PGI and PGI) were an independent predictor for an increased risk of gastric cancer even during a

follow-up of 10 years. In the multi-variate model, the strongest predictor was a low PGI/PGII-ratio, which is an indicator for mucosal atrophy in the GastroPanel® marker profile.

### **The acetaldehyde-related studies produced new significant findings**

During 2016, a new clinical acetaldehyde study in Uppsala University Hospital was concluded. The study compared the effect of Acetium capsule and placebo on the acetaldehyde levels in the gastric juice after alcohol intake in volunteers who had an atrophic gastritis (acid-free stomach) confirmed by GastroPanel® test and biopsy. Like in the previous studies, Acetium reduced the acetaldehyde level in the gastric juice highly significantly (68%) as compared to placebo. Furthermore, the study is the first to confirm that the slow-release L-cysteine remains in the stomach for several hours and binds acetaldehyde into a harmless MTCA-compound. These results were published in the November 2016 issue of Scandinavian Journal of Gastroenterology.

Acetium has been in use by Japanese cancer researcher for quite a long time by now. In Akita University the research group of Professor Katsunori Iijima (Head of Gastroenterology Department) has conducted further studies assessing the impact of Acetium on the internal acetaldehyde levels in the oesophageal and gastric mucosa and its possible impact on preventing the recurrence of cancer among the high-risk patients. GastroPanel® examination developed by Biohit Oyj is a significant tool in assessing the cancer risk of these patients.

### **Awareness of acetaldehyde was increased**

During 2016 the awareness of the harmfulness of acetaldehyde was increased in several occasions. In conjunction with the Annual Medical Assembly professor Mikko Salaspuro held a presentation about acetaldehyde as the most common carcinogen in the world. The presentation provoked a lively public discussion. Professor Salaspuro held a presentation about the same topic also in 8th Annual Charles Lieber Satellite Symposium in New Orleans on 25 June 2016. The presentation was called 'Acetaldehyde a neglected human carcinogen' and its summary is published in an international serie 'Experimental and Molecular Pathology 102: 2017'.

In the light of the current knowledge, the packages of alcoholic beverages should contain a statement on its possible content of acetaldehyde, which is classified by the WHO as a human carcinogen. Given that there is no scientific evidence to indicate that acetaldehyde and ethanol in the foodstuffs are less carcinogenic than acetaldehyde in alcoholic beverages, the same requirements should also apply to these products. Several alcoholic beverages and foodstuffs have an acetaldehyde content in excess of 5mg/L, which is the recommended upper limit for the acetaldehyde content in cosmetic products. Additionally, a scientific committee set by the EU has proposed in 2012 that mouthwashes should not contain acetaldehyde at all.

## **INVESTMENTS**

Gross investments during the 1-12/2016 reporting period totalled EUR 0.1 million (EUR 0.2 million), of which the second half year accounted for EUR 0.0 million (EUR 0.0 million). Key investments in the period were related to production automation-related equipment.

## PERSONNEL

During the review period, the Biohit Group employed 53 (52 in 2015) people on average. 44 (44) of whom were employed by the parent company and 9 (8) by the subsidiaries. At the end of the year 2016, the Group employed 49 (49) personnel, of whom 40 (40) were employed by the parent company and 9 (9) by the subsidiaries.

## SHORT-TERM RISKS AND UNCERTAINTY FACTORS

Biohit's key risks are related to the investments required for business growth and adequacy of economic resources these require in the medium term. Company's management assessment is that company's ability to continue its operations is good and there are no indications towards events or circumstances that alone or together might give a significant reason to doubt the organisation's ability to continue its operations in the next 12-month-period.

Other risks are involved in areas such as the success of clinical trials, the selection and development of new market areas and distribution channels, personnel recruitment, registration processes, product pricing, and political decision-making affecting the progress of screening programs. Significant short-term risks are associated with the successful selection of new market areas, the timing of expansion into selected markets and product success in these markets. The recent increase in uncertainty factors associated with international politics may have an unfavorable impact on the company's business.

The duration of the product registration process is different in each market area. For this reason, it is not possible to accurately assess the time taken for the authorities to handle registrations in these areas and for product sales to begin.

When investing liquid assets, the objective is to gain a return on investment with a minimum risk of equity loss. The investment portfolio consists of deposits, money market investments and corporate loans. A fundamental aspect in portfolio management is sufficient diversification across different asset classes, investment instruments and counterparties. Biohit conducts its investment activities with at least two partners.

Biohit's operation's customer base is widely diversified, with the exception of GastroPanel® sales in China, which currently represents a major single business for Biohit. Due to this reason, the company is dependent on the continuation of this business relationship. Otherwise, the company is not significantly dependent on individual customers or project deliveries. Most of the company's

business is conducted in euro, and the indirect effects of currency exchange rate fluctuations are considered insignificant.

## OUTLOOK FOR 2017

Together with its distributors and license partners Biohit has several product registrations ongoing in a number of different markets, which is affecting net sales development. A number of such registrations are expected to be completed in 2017. In addition, negotiations are in progress with new partners, including on the launch of major screening projects, but a number of political risks are affecting the progress of such projects.

China's operations are in Biohit's focus in 2017. In addition to the ongoing screening studies Biohit's joint venture Biohit HealthCare (Hefei) Co. Ltd has succeeded in building a wide distributor network and customer base as well as in commercialising GastroPanel® widely, making use of the previous work on gaining price approval decisions in Chinese provinces. Development of sales has been good and increasing, especially in the second half of the year. The joint venture is well positioned to continue this work also in 2017. Biohit expects to complete the reduction of the joint venture share capital during the first quarter of 2017. As a result of the transaction Biohit Oyj estimates its non-comparable operating result to turn clearly positive for 2017. Reduction of the entire share capital of the joint venture is a part of our future GastroPanel® strategy in China. Establishing a production plant, receiving the needed licenses and commercialisation of the new product required sharing the risk in the means of a joint venture but for a company, which is completely Chinese-owned, is easier to get an access to national health care programs and growth funding than for a company, which is partly foreign-owned.

Biohit's cost structure is characterised by high investment in research to obtain further evidence on the efficacy of Biohit's diagnostic tests in various clinical settings and in population-based screenings. Late 2016 Biohit announced GastroPanel® quick test. GastroPanel® quick test differs from the current version by being able to give the result already during a single clinical appointment. GastroPanel® quick test is available in Europe after the performance and clinical tests required by the CE certification process are completed.

We also facilitated the access to our health tests. R-kioski convenience stores are selling and marketing gift cards for Biohit Oyj's health checks for consumers.

We aim to grow profitable and are strongly committed to taking necessary actions in order to build a profitable future for the company. Net sales growth is expected in 2017. The company does not assess when the comparable result will turn to positive.

## BOARD'S PROPOSAL FOR DISTRIBUTIONS OF PROFIT

The parent company's distributable funds (unrestricted equity) on 31 December 2016 are EUR 5,479,775.77, of which the period net loss is EUR 2,580,940.29. The Board of Directors proposes to the Annual General Meeting that no dividend be paid for the financial year.

## MAIN EVENTS IN THE SECOND HALF OF THE YEAR (H2)

### **Beijing HuayiHuilang Medical Instrument Co., Ltd. to distribute GA-map™ Dysbiosis Test in China**

Biohit Oyj and Beijing HuayiHuilang Medical Instrument Co., Ltd. signed an agreement for the distribution of the GA-map™ Dysbiosis Test in China.

### **Ilari Patrakka appointed Biohit Oyj's Sales and Marketing Director**

Ilari Patrakka was appointed Biohit Oyj's Sales and Marketing Director and as a member of the Management Team as of August 26th 2016. He holds a Master of Science (M.Sc.) degree in Business Administration.

### **Glomedics to distribute Biohit Lactose Intolerance Quick Test in South Korea**

Biohit Oyj and Glomedics signed an agreement for the distribution of the Biohit Lactose Intolerance Quick Test in South Korea.

### **The first meta-analysis of the scientific studies conducted with GastroPanel® was completed – the test is accurate for diagnosing atrophic gastritis**

The first meta-analysis of the scientific studies conducted with GastroPanel® test was completed. GastroPanel® is a unique, very informative test for examining patients with upper stomach problems and diagnosing helicobacter gastritis (infection) and atrophic gastritis developed from it and stomach cancer and other risks caused by atrophic gastritis. Atrophic gastritis, which is usually asymptomatic and which 13C urea breath test, fecal antigen test or pure antibody tests can not detect, can be detected only with GastroPanel® or gastroscopy and biopsy examination. Possibly for this reason, a stomach cancer developed from atrophic gastritis is still diagnosed at late stages, when the prognosis is very poor ([www.biohithealthcare.com/additional-information](http://www.biohithealthcare.com/additional-information)).

### **Biohit Oyj's Chinese joint venture to start production - Gastric cancer risk screening study progressing in China**

Biohit Oyj's Chinese joint venture Biohit HealthCare (Hefei) Co. Ltd production facility passed official test requirements and was granted a license enabling production and sales of products. Biohit HealthCare (Hefei) Co. Ltd will start manufacturing of the globally unique GastroPanel®-product developed by Biohit Oyj for the Chinese market. The first shipments will go to fill orders relating to the ongoing gastric cancer risk screening study.<

### **Acetium capsule prevents the exposure to carcinogenic acetaldehyde in patients with atrophy of the stomach mucosa**

New scientific evidence on Acetium capsule was obtained. A collaborative study with Uppsala University shows that Acetium capsule prevents acetaldehyde exposure in patients suffering from the atrophy of the stomach mucosa (atrophic gastritis) caused by *Helicobacter pylori* infection.

### **Biohit Oyj's GastroPanel® quick test**

GastroPanel® test's performance and clinical tests as well as registration can be potentially be completed already during 2017. This quick test can be performed during a clinical appointment from a fingertip blood drop. The new test is an advanced version of Biohit's unique GastroPanel® stomach health test ([www.biohithealthcare.com/additional-information](http://www.biohithealthcare.com/additional-information)). GastroPanel® quick test differs from the current clinical test version by giving the results immediately during a single clinical appointment. The GastroPanel® quick test saves costs and unnecessary clinical appointments as well as speeds up the referral to further examinations and eventual treatment, which significantly improves the patient safety.

### **Biohit Oyj and R-kioski to start cooperation**

Biohit Oyj and R-kioski started cooperation. R-kioski will sell and promote the gift cards for Biohit's health checks for its consumers in R-kioski convenience stores across Finland. The agreement will enter into force immediately and will start with a launch during December 2016.

### **Biohit Oyj's Option Scheme I 2013 – Management Option Arrangement**

Biohit Oyj's Board of Directors decided on December 5, 2016 to distribute option rights of the option scheme I 2013 as follows: Graham Johnson 30.000 pcs, Panu Hendolin 30.000 pcs, Niklas Nordström 30.000 pcs, Daniela Söderström 30.000 pcs and Ilari Patrakka 30.000 pcs. For the option rights share subscription period commences on January 1, 2017 and ends on May 31, 2019. The persons have accepted the option rights.

### **Biohit Oyj's Financial Reporting and Annual General Meeting in 2017**

Biohit Oyj will release its financial statements for 2016 on Monday 20<sup>th</sup> of February 2017. The Annual Report, which contains the Financial Statements for 2016 and the Report of the Board of Directors will be published approximately during week 12. Biohit Oyj's Annual General Meeting has been planned for Wednesday 26<sup>th</sup> of April 2017 at 5:00 pm. Half year financial report for period January-June (H1) 2017 will be published on Thursday 17<sup>th</sup> of August 2017.

### **Possible to send a whole blood sample for GastroPanel® examination**

Biohit has now subjected the GastroPanel® examination for further refinements, of which a patent application has been recently submitted. Now a whole blood sample can be sent to GastroPanel® examination without additional processing steps in context of drawing the sample, like



centrifugation and transfer of the plasma (separated from a whole blood sample) into a tube with patient's data label. This gives only in Europe the possibility for the thousands of private practices to take GastroPanel® as part of their test assortment with its benefits. Furthermore, by collecting whole blood samples, the risk of stomach and oesophagus cancer, with GastroPanel® screening, which provide plenty of other information as well, could be even easier to realise in a cost efficient way ([www.gastropanel.com](http://www.gastropanel.com), [www.biohithealthcare.com/additional-information](http://www.biohithealthcare.com/additional-information) ).

## MAJOR EVENTS AFTER THE CLOSE OF THE PERIOD

### **Ownership arrangement in Biohit Oyj's Chinese Joint Venture – 2017 operating result expected to be positive**

Biohit Oyj and Anhui Wisdom-Win Investment Co. Ltd signed a resolution authorised by shareholders of Biohit HealthCare (Hefei) Co. Ltd. a joint venture operating in Hefei, China, concerning reduction of the joint venture share capital for an amount equal to Biohit Oyj's shareholding. Biohit Oyj owns 40% of the company, and the agreement is for reduction of the entire share capital. As a result of the transaction Biohit Oyj estimates its operating result to turn calculatory positive for 2017. The transaction requires approval from the authorities.

Biohit Oyj does not classify Biohit HealthCare (Hefei) Co. Ltd shares as an asset available for sale as the book value of the asset is not in principal determined by the assets transaction value and the share capital reduction requires approval from the authorities.

## ADMINISTRATION

### **Biohit's financial reporting and Annual General Meeting in 2017**

Biohit Oyj's Annual General Meeting has been planned for 5.00 pm on Wednesday 26 April 2017 in Helsinki. The Board of Directors will call the General Meeting at a later date. In 2017 the company will publish the half-year report for period January - June 2017 (H1) at 9:30 am on Thursday 17 August 2017.

### **Biohit Oyj's Management Team**

The members of Biohit's Management Team are: CEO Semi Korpela, CFO Niklas Nordström, Director of Business Development Lea Paloheimo, Production & Research and Development Director Panu Hendolin, Sales and Marketing Director Ilari Patrakka, Quality and Regulatory Affairs Director Daniela Söderström and Chief Medical Director Kari Syrjänen.

## SHARES AND SHAREHOLDERS

Biohit Oyj's number of shares is 14,698,533 (14,348,533), of which 2,975,500 (2,975,500) are Series A shares and 11,723,033 (11,373,033) are Series B shares. The Series B shares are quoted on NASDAQ Helsinki in the Small cap/Healthcare group under the code BIOBV.

Supposing that the market capitalisation for series A and B shares is equal, the total market capitalisation at the end of the period was EUR 88.9 million (EUR 80.5 million on 31 December 2015). Shares' trade value during the period amounted to approximately EUR 12 million.

BIOBV/NASDAQ OMX Helsinki	1-12/2016	1-12/2015
High (EUR)	6.42	7.14
Low (EUR)	4.71	4.22
Average (EUR)	5.57	5.45
Latest (EUR)	6.05	5.61
Turnover (EUR)	11,988,747	22,618,230
Turnover volume	2,158,791	4,014,402

## Shareholders

At the end of the reporting period on 31 December 2016, the company had 6,402 shareholders (6,594 on 31 December 2015). Private households held 76.17% (78.0%), companies 19.26% (20.1%) and public sector organisations 0.02% (0.0%). Foreign ownership or nominee registrations accounted for 4.41% (1.7%) of shares.

Further information on the shares, major shareholders and management shareholdings is available on the company's website at [www.biohithealthcare.com/investors](http://www.biohithealthcare.com/investors).

## ACCOUNTING PRINCIPLES

This financial statement release has been prepared in accordance with the requirements of the IAS 34 Interim Financial Reporting standard. Biohit Oyj has applied the same accounting principles in preparing this financial statement release as for its financial statements 2015.

The figures in the financial statement release have not been audited.

## CONSOLIDATED INCOME STATEMENT

EUR million	7- 12/2016	7- 12/2015	Change	1- 12/2016	1- 12/2015	Change
<b>Net sales</b>	4.4	2.5	1.8	8.2	6.1	2.1
Materials and services	-2.2	-1.4	-0.9	-4.0	-2.9	-1.1
<b>Gross margin</b>	2.1	1.2	1.0	4.2	3.2	1.0
Other operating income	0.1	0.7	-0.7	0.1	0.8	-0.6
Sales and marketing	-1.1	-1.1	0.1	-2.2	-2.3	0.1
Administration	-1.8	-1.2	-0.6	-3.3	-2.4	-0.9
Research and development	-0.8	-1.0	0.1	-2.0	-2.0	0.1
Share of profit/loss in Joint Venture	0.2	-0.1	0.3	-0.2	-0.1	-0.1
<b>Operating profit/loss</b>	-1.3	-1.4	0.2	-3.4	-2.9	-0.5
Financial income	0.2	0.1	0.1	0.2	0.2	0.0
Financial expenses	0.0	-0.2	0.2	-0.2	-0.2	0.1
<b>Profit/loss before taxes</b>	-1.2	-1.6	0.4	-3.3	-2.9	-0.4
Income taxes	0.0	0.0	0.0	0.0	0.0	0.0
<b>Profit/loss for the period</b>	-1.2	-1.6	0.4	-3.3	-2.9	-0.4
Other comprehensive income after taxes						
Other comprehensive income to be reclassified to profit or loss in subsequent periods						
Available-for-sale financial assets	0.5	0.0	0.5	1.0	-0.2	1.1
Translation differences	0.0	0.0	0.0	-0.1	0.0	-0.1
Other comprehensive income to be reclassified to profit or loss in subsequent periods	0.4	0.0	0.5	0.9	-0.2	1.0
<b>Total comprehensive income for the period</b>	-0.8	-1.6	0.9	-2.4	-3.1	0.7

Earnings per share calculated from earnings attributable to equity holders of the parent company

	1-12/2016	1-12/2015
Undiluted earnings per share (EUR)	-0.22	-0.20

**CONSOLIDATED BALANCE SHEET**

MEUR	31.12.2016	31.12.2015
<b>ASSETS</b>		
<b>NON-CURRENT ASSETS</b>		
Intangible assets	1.2	1.4
Tangible assets	0.7	0.8
Share in Joint Venture	0.4	0.6
Other financial long-term assets	0.0	0.0
Deferred tax assets	0.1	0.1
<b>Total non-current assets</b>	<b>2.4</b>	<b>2.9</b>
<b>CURRENT ASSETS</b>		
Inventories	0.9	0.6
Trade and other receivables	2.0	1.0
Other financial short-term assets	7.1	6.5
Cash and cash equivalents	0.6	0.7
<b>Total current assets</b>	<b>10.6</b>	<b>8.9</b>
<b>TOTAL ASSETS</b>	<b>13.0</b>	<b>11.7</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>		
Shareholders' equity attributable to the owners of the parent company		
Share capital	2.4	2.4
Invested unrestricted equity fund	4.3	2.4
Translation differences	-0.1	0.0
Retained earnings	4.1	5.6
<b>Total shareholders' equity</b>	<b>10.7</b>	<b>10.3</b>
<b>NON-CURRENT LIABILITIES</b>		
Deferred tax liabilities	0.4	0.2
Other liabilities	0.0	0.0
<b>Total non-current liabilities</b>	<b>0.4</b>	<b>0.2</b>
<b>CURRENT LIABILITIES</b>		
Trade payables	1.0	0.3
Total interest-bearing liabilities		0.1
Tax liabilities	0.0	0.0
Other liabilities	0.8	0.8
<b>Total current liabilities</b>	<b>1.8</b>	<b>1.2</b>

Total liabilities	2.2	1.4
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES	13.0	11.7

## STATEMENT OF CHANGES IN EQUITY

### Consolidated statement of changes in equity on 31 December 2016

MEUR	Share capital	Invested unrestricted equity fund	Translation differences	Fair value reserve	Retained earnings	Shareholders' equity
Shareholders' equity 1 Jan 2016	2.4	2.4	0.0	0.0	5.5	10.3
Direct share issue		2.0				2.0
Share based payments					0.9	0.9
Total comprehensive income for the period			-0.1	1.0	-3.3	-2.4
Shareholders' equity 31 December 2016	2.4	4.3	-0.1	1.0	3.1	10.7

### Consolidated statement of changes in equity on 31 December 2015

MEUR	Share capital	Invested unrestricted equity fund	Translation differences	Fair value reserve	Retained earnings	Shareholders' equity
Shareholders' equity 1 Jan 2015	2.4	1.9	0.0	0.2	8.2	12.7
Share based payments					0.2	0.2
Exercise of share options		0.5				0.5
Total comprehensive income for the period			0.0	-0.2	-2.9	-3.1

Shareholders' equity 30 Dec 2015	2.4	2.4	0.0	0.0	5.5	10.3
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## CONSOLIDATED CASH FLOW STATEMENT

MEUR	1-12/2016	1-12/2015
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>		
Loss for the period	-3.3	-2.9
Adjustments	1.3	0.0
Change in working capital	-0.5	-0.2
Interest paid and payments on other operating financial expenses	-0.1	-0.2
Interest received	0.3	0.2
Realised exchange rate gains and losses	0.0	0.0
Income taxes paid	-0.1	-0.1
<b>Net cash flow from operating activities</b>	<b>-2.5</b>	<b>-3.1</b>
<b>CASH FLOW FROM INVESTMENTS</b>		
Investments in tangible and intangible assets	-0.1	-0.2
Proceeds from disposal of tangible and intangible assets	0.0	0.1
Net investments in funds and deposits	2.6	3.0
<b>Net cash flow from investments</b>	<b>2.5</b>	<b>2.9</b>
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>		
Rights issue		0.5
Repayment of loans	-0.1	-0.1
<b>Net cash flow from financing activities</b>	<b>-0.1</b>	<b>0.4</b>
Increase (+)/decrease (-) in cash and cash equivalents	-0.1	0.1
Cash and cash equivalents at the beginning of the period	0.7	0.6
Effect of exchange rates on cash and cash equivalents	-0.1	0.0
<b>Cash and cash equivalents at the end of the period</b>	<b>0.6</b>	<b>0.7</b>

## RELATED PARTY TRANSACTIONS



Biohit Oyj's goods and service sales for our joint venture Biohit Healthcare (Hefei) Co. Ltd increased significantly during the financial period compared to previous year being EUR 3.6 million (EUR 1.4 million in 2015 including the closely associated company Anhui Machinery Development).

### Biohit Oyj B-shares subscribed with stock options I and II 2013 during the 1-12/2016 reporting period

During 2016 no new Biohit Oyj shares were subscribed for with stock options I 2013.

As a result of the directed share issue for Genetic Analysis AS in 2016 (350,000 shares), the total number of Biohit Oyj's shares increased to 14,698,533 (14,348,533 shares December 31, 2015) and B-shares to 11,723,033 (11,373,033 shares December 31, 2015). The new shares will correspond to a percentage of 2.38% of Biohit Oyj's total number of shares and 0.49% of the voting rights after registration.

## COLLATERAL, CONTINGENT LIABILITIES AND OTHER COMMITMENTS

	31.12.2016	31.12.2015
<b>Collateral granted on behalf of the parent company</b>		
Guarantees	0.1	0.0
<b>Collateral granted on behalf of the subsidiaries</b>		
Guarantees		
<b>Other liabilities</b>		
<i>Leasing commitments</i>		
Due for payment in less than one year	0.1	0.0
Due for payment in more than one year but less than five years	0.1	0.0
Due for payment in more than five years	0.0	0.0
<b>Total</b>	<b>0.1</b>	<b>0.1</b>
<i>Other rental commitments</i>		
Due for payment in less than one year	0.3	0.2
Due for payment in more than one year but less than five years	0.5	0.6
Due for payment in more than five years		
<b>Total</b>	<b>0.7</b>	<b>0.9</b>
<b>Other contingent liabilities</b>	<b>0.8</b>	<b>0.9</b>
<b>Collateral and contingent liabilities total</b>	<b>0.9</b>	<b>0.9</b>

## NEXT FINANCIAL REPORT

The half-year report for January - June 2017 (H1) will be published at 9:30 am local time (EEST) on Thursday 17 August 2017.

**Helsinki, 20 February 2017**

Biohit Oyj  
Board of Directors

**Additional information:**

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*Biohit in brief*

*Biohit Oyj is a globally operating Finnish biotechnology company. Biohit mission is “Innovating for Health” – we produce innovative products and services to promote research and early diagnosis. Biohit is headquartered in Helsinki, Finland, and has subsidiaries in Italy and the UK. Biohit Series B share (BIOBV) is quoted on Nasdaq Helsinki in the Small cap/Healthcare group.*

[www.biohithealthcare.com](http://www.biohithealthcare.com)