

Q3 2016

Third Quarter 2016



# Highlights for the third quarter of 2016

- O Group sales increased to NOK 21.1 million in the third quarter of 2016 from NOK 16.4 million in the third quarter of 2015
- O EBITDA was NOK -5.9 million in the third quarter of 2016 compared to NOK -3.5 million in the third quarter of 2015, reflecting a high activity level in commercialization of Woulgan®
- O Received confirmation of reimbursement for Woulgan® by one of the largest insurance companies for two regions in Germany
- O ArcticZymes launched the first product in the Polymerase portfolio

# **Key Financials**

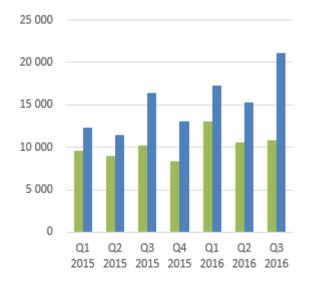
Amount in NOK 1.000	Q3 2016	Q3 2015	9M 2016	9M 2015
Sales	21 115	16 410	53 689	40 219
EBITDA	-5 883	-3 502	-10 952	-7 290
EBIT	-6 438	-4 200	-12 480	-9 340
Net cash flow from operations	-2 937	-1 219	-16 610	-15 220
Net cash end of period	61 734	76 941	61 734	76 941



# Biotec Pharmacon – Group Figures

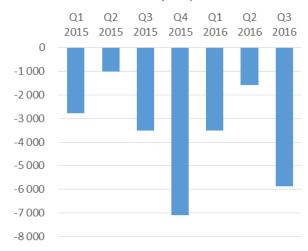
Biotec Pharmacon ASA, (hereinafter "Biotec" or "the Company") reported sales of NOK 21.1 million (16.4) for the third quarter of 2016. EBITDA was NOK -5.9 million (-3.5) and EBIT NOK -6.4 million (-4.2) in the quarter. Net financial income was NOK 0.2 million (-0.5), generating an earnings before tax of NOK -6.2 million (-4.7) for the quarter.





The beta-glucan segment reported strong growth in sales, with NOK 15.1 million of sales compared to NOK 11.0 million during the third quarter of 2015. The enzyme segment had third guarter 2016 sales of NOK 6.0 million compared to NOK 5.4 million in the third quarter of 2015. For the first nine months, group sales increased to NOK 53.7 million, from NOK 40.2 million in the first nine months of 2015. The group had a gross contribution of NOK 10.8 million (10.2) in the third quarter of 2016 and a gross contribution of NOK 34.5 million (28.8) for the first nine months of 2016. The increased sales of beta-glucans in the third quarter did not lead to increased gross contribution due to change of the product mix.

### EBITDA per quarter



Reduction in EBITDA for the third quarter of 2016, compared to the same quarter last year, is mainly due to increased commercial activities relating to the Woulgan® and low sales in the nutrition segment.

The group had 40 employees at the end of the third quarter, compared to 36 employees at the end of the third quarter of 2015. Most of the added positions are related to commercial activities in Woulgan®

#### **Balance Sheet**

Total equity amounted to NOK 76.0 million at the end of the third quarter 2016 compared to NOK 86.7 million at the end of 2015.

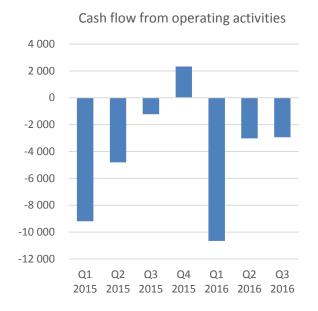
Total assets were NOK 88.9 million at the end of the third quarter of 2016, compared to NOK 101.1 million at the end of 2015. The Company has no interest-bearing debt.

#### **Cash Flow**

Net cash flow from operating activities was NOK -2.9 million in the third quarter 2016, compared to NOK -1.2 million in the same quarter in 2015. The operating cash flow reflects a change in

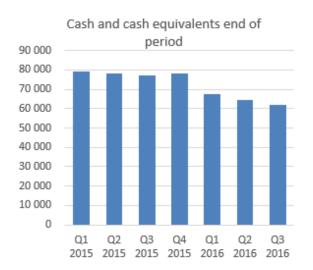


working capital of NOK 7.4 million compared to end of fourth quarter 2015. This is due to normal fluctuations in the working capital.



Net cash flow from investing and financing activities was NOK 0 in the third quarter, as well as for the first nine months of 2016.

Changes in cash and cash equivalents were NOK -2.9 million in the third quarter and NOK -16.6 million for the first nine months. This generated a cash balance of NOK 61.7 million at the end of the quarter, compared to NOK 78.3 million at the end of 2015.



#### **Shareholder matters**

The total number of issued shares was 43,944,673 at the end of the third quarter of 2016. The number of issued employee share options was 1,167,750 at the end of the quarter. In total 203,250 of these share options can be exercised in 2016.



#### **Risk factors**

Biotec's business is exposed to a number of risk factors that may affect parts or all of the Company's activities. There are no substantial changes in the risk factors, which are described in the annual report for 2015, published on the Company's web site www.biotec.no.



# Business areas reporting:

# Beta-glucans

Biotec Pharmacon continues to build commercial traction for Woulgan® in the UK, the Nordic countries and Germany. There has been a strong demand for the Company's animal health product and Biotec is currently exploring new opportunities in the nutrition segment.

## Woulgan® - UK

The follow-up of the UK clinical focus group that was announced earlier, show further progress for several patients. The goal of the study was to demonstrate Woulgan's ability to heal various types of stalled wound in a real world context. The experiences and results provide valuable guidance to health care professionals on the best use for Woulgan®. The updated data also demonstrates how Woulgan® would be cost effective by healing more patients faster than standard treatments, which is a key consideration for the Drug Tariff.

An updated analysis has been submitted to the UK Drug Tariff as part of a response to further questions received in September.

The first clinician, who was also involved in the focus group, has successfully added Woulgan® onto their latest specialist formulary, which will be launched at the end of November 2016. It means they will use Woulgan® regularly on stalled wounds regardless of reimbursement. This acknowledgement of Woulgan® further brings an important reference in the UK market penetration.

The main UK activities during the third quarter have been to continue reporting case series and to prepare for commercial launch.

## Woulgan® - Nordic

Biotec and its distribution partner Navamedic have continued a high level of activities in the Nordic countries through extensive marketing and product positioning.

In the Nordic market, local key opinion leaders (KOL's) must be convinced of the product benefits before Woulgan® will gain significant commercial traction. Subsequent sales will be dependent on the product being listed in local tenders and supported by KOL recommendation. The first tender was obtained earlier this year in Helsinki, which is the largest region in Finland, and several other Finnish tenders are under review. In Sweden the first tender has been obtained in a small region but with some important wound care clinics. In Norway, the first tender feedback is expected soon and additional regions will be open for submission within the next few months. There are also a number of initiatives on-going in Denmark.

## Woulgan® - Germany

Germany, Europe's largest health care market, with estimated 240,000 stalled wounds, is highly regionalized and funded by a large number of insurance companies (Krankenkassen). Biotec has obtained confirmation from one of the largest insurance companies that Woulgan® will be reimbursed for two of the main regions. This is encouraging and Biotec anticipates other regions and insurance companies to follow.

Our distributor Rogg Verbandstoffe (Rogg) is selling to general practitioners and their associated pharmacies. All of Rogg's Key Account Managers have now received sales training and have started promoting Woulgan®. The initial feedback from users are positive and the first commercial sales are received.



In Germany, many wounds are treated by homecare providers offering walk-in wound care clinics and home treatment. The top homecare companies are large organizations with central purchasing functions, which make them an efficient segment for Biotec to target directly. Biotec has recently signed its first supply agreement with a mid-size homecare provider and training of the clinical staff is scheduled for a launch meeting in November 2016. This is an important milestone in broadening the commercialization of Woulgan® in Germany.

At a national level in Germany, there is an ongoing process of reviewing the reimbursement system. Biotec is monitoring this process to understand any potential consequences for Woulgan®.

## Woulgan® - USA

In June 2016, Biotec submitted a 510K application to the Federal Drug Administration (FDA). The Company has recently received feedback from the FDA confirming that the evaluation of the application has started. As previously outlined, a 510K approval alone does not give the product a reimbursement that is required for commercial success in the USA, but represents an important regulatory step in the process of US commercialization. Thus, a 510K may not lead to a commercial launch in US. This process will be reconciled with the feedback from the partner process and the ongoing reimbursement evaluation to develop the optimal strategy for the product positioning in this important market.

### Woulgan® - Other

During the third quarter of 2016, four sites in the UK, in addition to one Swedish site, are recruiting patients for the Post Market Clinical Follow-Up Study. The randomised controlled trial aims to recruit a total of 80 patients suffering from diabetic foot ulcers, of which 60 will be treated with Woulgan® and 20 with the product Intrasite® as the comparator. Intrasite® is one of the leading hydrogel products in the market

## Beta-glucans - Other

The ongoing clinical study at Memorial Sloan Kettering has recruited 92 patients at the end of the third quarter of 2016. The neuroblastoma patients are treated with the combination of an experimental cancer vaccine developed by Memorial Sloan Kettering Cancer Centre and Soluble Beta Glucan (SBG®) from Biotec. SBG® is used for its immunomodulatory properties. The study aims to recruit a total of 115 patients, whereof 100 are treated under phase II of the protocol, focusing on efficacy of the combination treatment.

During the third quarter, Biotec has renewed the manufacturing licence for clinical trial use of SBG and was successfully audited by the Norwegian Medicines Agency.

Following the ruling by the Arbitration Court in favour of Biotec earlier this year, the Company is exploring the opportunities of a more direct involvement in the nutrition market. So far, no concrete decision has been taken to alter our position.

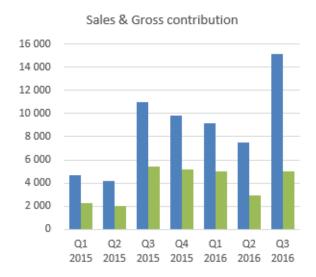
Sales growth remains strong with the feed ingredient product M-Glucan®. The current customer base is limited to the salmon farming area, but Biotec is also exploring opportunities in other feed sectors.

#### Financial review beta-glucans

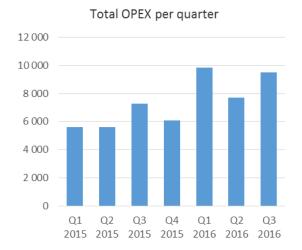
BBG sales amounted to NOK 15.1 million in the third quarter of 2016, compared to NOK 11.0 million in the third quarter of 2015. Sales for the first nine months was in total NOK 31.8 million compared to NOK 19.9 million in the same



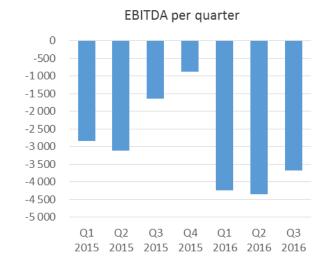
period of 2015. The increase is due to extraordinary sales within the animal health segment which is not expected to continue on the same level into the fourth quarter.



Operating expenses increased from NOK 7.3 million in the third quarter of 2015 to NOK 9.5 million in the third quarter of 2016, mainly due to increases in personnel expenses and external services for the commercialization of Woulgan®. Operating expenses for the first nine months have increased from NOK 18.5 million in 2015 to NOK 27.1 million in 2016. Biotec expects this cost level to continue, as Woulgan® is being launched and commercialized in several markets.



EBITDA for the third quarter of 2016 was NOK -3.7 million compared to NOK -1.6 million in the same period last year. For the first nine months, EBITDA was NOK -12.3 million compared to NOK -7.6 million at the same time last year.





# Enzymes (ArcticZymes)

#### **Business**

Enzyme sales reached NOK 6.0 million in the third quarter and NOK 21.9 million for the first nine months. The sales development to date is a combination of growth in existing business with existing customers, new business from existing customers and bringing on board new, strategically relevant customers. ArcticZymes continues to broaden its sales into new market and regions, becoming less dependent on a few major customers.

ArcticZymes' commercial efforts to create business is most evident in the third quarter across the geographical regions:

- In Europe, it has been a busy quarter with new business in the Molecular Diagnostics (MDx) area. A new 4 year supply agreement was signed with a global MDx company.
   Several other negotiations are ongoing with similar companies in Europe with the aim to capture long-term value through a wider customer base.
- In North America, the merger of the two largest customers has resulted in discontinuation of some of their products, leading to reduced volumes from ArcticZymes. This has been compensated by new sales through new customers and growth in other existing business.
- In rest of the world, the Company and the OEM partners have seen strong growth even though numbers are still small with additional growth and partners on the horizon.

ArcticZymes was granted a U.S. patent (US9422595) protecting the intellectual property for HL-SAN. The approval of the new patent in the U.S. strengthens ArcticZymes' rapidly growing intellectual property portfolio.

The patent extends protection in the US to the nucleic acid sequence of its HL-SAN product. The patent fits timely with the commercial efforts for the SAN portfolio, where these enzymes have typically been utilized by the customers in the preparation of nucleic acidfree products such as recombinant proteins and reagents. More recently, ArcticZymes has gained growing interest from manufacturers of adeno-associated virus (AAV) for utility in gene therapy. The new patent strengthens ArcticZymes' commercial efforts. During this year, the Company has experienced a sharp upturn of sample requests to evaluate SAN, which has even extended to potential utility by Pharmaceutical companies.

ArcticZymes launches its first DNA polymerase as part of a new portfolio offering. The IsoPol™ DNA Polymerase is a novel isothermal polymerase with distinct properties, compared to other enzymes. For ArcticZymes, the Isothermal polymerase portfolio represents both a commercial potential and a strategic positioning of a product that could prove to be more important than any of the Company's existing products. Development activities will now be focused towards phase 2, where ArcticZymes plans to commercialize additional novel variants of IsoPol<sup>™</sup> DNA Polymerase during the next 2 years. Prior to launch, several global life science and diagnostic organizations have begun to evaluate the IsoPol<sup>™</sup> DNA Polymerase for potential incorporation into their next generation technology platforms.

#### **Financial review Enzymes**

Sales in ArcticZymes amounted to NOK 6.0 million in the third quarter of 2016, up from NOK 5.4 million in the same quarter last year. Total sales for the first nine months were NOK 21.9 million compared to NOK 20.3 million at the same time in 2015. ArcticZymes sales is



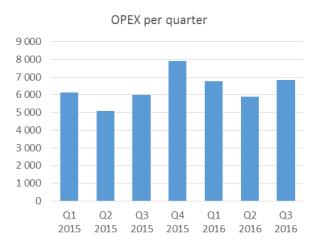
characterized by larger orders to a limited number of customers. This will continue to give fluctuations in sales per quarter going forward.



Other revenues for the first nine months of 2016 showed a decrease from NOK 4.2 million in 2015 to NOK 3.2 million in 2016.

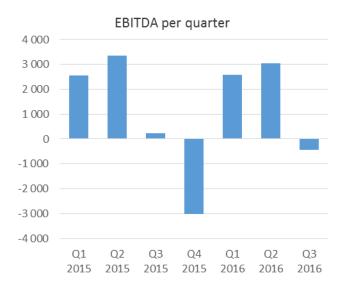
Operating expenses have increased from NOK 6.0 million in the third quarter of 2015 to NOK 6.8 million in the third quarter of 2016, mainly because of increased personnel expenses.

Operating expenses for the first nine months have increase from NOK 17.2 million in 2015 to NOK 19.5 million in 2016.



EBITDA show a loss of NOK 0.4 million for the third quarter of 2016, a reduction from positive NOK 0.2 million in the same quarter of 2015.

EBITDA for the first nine months was a profit of NOK 5.2 million compared to a profit of NOK 6.2 million in the first 9 month of 2015



# **OUTLOOK**

Biotec continues to have a strong commercial focus in all business segments while continuing to develop the next generation of products.

Focus in the wound care segment is to position Woulgan ® as the key product for stalled wounds. This market represents an opportunity of at least USD 100 million in-market sales for the Woulgan® product platform.

Biotec reiterates its operational 2016 targets for Woulgan®. Finalising the UK reimbursement process and driving sales in the UK have not been achieved as per end of the third guarter.

Biotec awaits UK Drug Tariff approval before a UK launch can be effectively pursued.

The Woulgan® 510K is being processed at the FDA and some feedback has been received. A 510K application typically takes 6-9 months to complete, which should indicate a conclusion in the first quarter of 2017. However, a new unique substance like Woulgan® may take



longer. The Company experienced such with the CE mark and the ongoing UK Drug Tariff process. Biotec will be thorough in the process of identifying a US partner, in order to ensure the best possible commercialization strategy.

Biotec BetaGlucans will focus on developing new and securing existing supplier agreements within animal health and nutrition, as well as pursuing opportunities within the field of cancer.

In the enzyme market, ArcticZymes has a strong product offering, in addition to valuable long-term relationships with key customers. Further development of the Company's partnerships in molecular, diagnostic and adjacent markets, should enable ArcticZymes to increase its market share in this growing market going forward.





# **Financial statement 3rd quarter 2016**

### **INCOME STATEMENT - THE GROUP**

		Q3	Jan - Sept.		
(Amounts in NOK 1.000 - exept EPS)	2016	2015	2016	2015	
Sales	21 115	16 410	53 689	40 219	
Cost of goods sold	-10 289	-6 224	-19 206	-11 430	
Gross profit	10 826	10 186	34 482	28 788	
Other revenues	1 384	1 704	4 979	5 504	
Sum other revenues	1 384	1 704	4 979	5 504	
Personell expenses	-11 644	-9 482	-30 582	-24 535	
Other expenses	-6 445	-5 910	-19 830	-17 047	
EBITDA	-5 883	-3 502	-10 952	-7 290	
Depreciation and amortization expenses	-555	-698	-1 529	-2 050	
EBIT	-6 438	-4 200	-12 480	-9 340	
Finanical income, net	235	-512	387	110	
ЕВТ	-6 204	-4 713	-12 094	-9 230	
Tax	0	0	0	0	
Earnings after tax	-6 204	-4 713	-12 094	-9 230	
Basic EPS (profit for the period)	-0,14	-0,11	-0,28	-0,21	
Diluted EPS (profit for the period)	-0,14	-0,11	-0,28	-0,21	

### **BALANCE SHEET - THE GROUP**

(Amounts in NOK 1.000)	2016-09-30	2015-09-30	2015-12-31
Non-current assets			
Machinery and equipment	3 144	4 570	4 118
Intangible assets	4 577	4 566	5 074
Other financial assets	2	80	77
Total non-current assets	7 723	9 216	9 269
Current assets			
Inventories	3 151	2 010	2 904
Trade receivables and other receivables	16 341	17 237	10 555
Cash and cash equivalents	61 733	76 941	78 343
Total current assets	81 225	96 187	91 802
Total assets	88 947	105 403	101 071
Equity			
Share capital	43 945	43 946	43 945
Share premium capital	133 378	133 376	133 378
Other equity	-101 968	-84 639	-91 064
Non-controlling interests	651	1 796	489
Total equity	76 006	94 479	86 749
Current liabilities			
Trade-, short term-, and other payables	12 941	10 924	14 322
Total current liabilities	12 941	10 924	14 322
Total equity and liabilities	88 947	105 403	101 071



### **CHANGES IN EQUITY - THE GROUP**

		Share				
		premium		Minority	Other	
(Amounts in NOK 1000)	Share capital		Own shares	interests	reserves	Total equity
Walter and Walter Coop	onaro capitar	oupitui			.000.700	rotal oquity
Balance at 2014-12-31	43 623	129 224	0	437	-74 417	98 867
Total comprehensive income/-loss for the period	0	0	0	52	-17 344	-17 292
Transactions with shareholders:						
Employee stock option provision	322	4 154	0	0	734	5 210
Purchase of own shares	0	0	-172	0	0	-172
Sale of own shares	0	0	137	0	0	137
Total transactions with shareholders	322	4 154	-35	0	734	5 175
Balance at 2015-12-31	43 945	133 378	-35	489	-91 027	86 750
Total comprehensive income/-loss for the period	0	0	0	0	-3 810	-3 810
Transactions with shareholders:						
Employee stock option provision	0	0	0	0	367	367
Total transactions with shareholders	0	0	0	0	367	367
Balance at 2016-03-31	43 945	133 378	-35	489	-94 470	83 307
Total comprehensive income/-loss for the period	0	0	0	188	-2 270	-2 082
Transactions with shareholders:						
Employee stock option provision	0	0	0	0	430	430
Total transactions with shareholders	0	0	0	0	430	430
Balance at 2016-06-30	43 945	133 378	-35	677	-96 311	81 655
Total comprehensive income/-loss for the period	0	0	0	-28	-6 176	-6 204
Transactions with shareholders:						
Employee stock option provision	0	0	0	0	555	555
Total transactions with shareholders	0	0	0	0	555	555
Balance at 2016-09-30	43 945	133 378	-35	650	-101 932	76 006

## CASH FLOW ANALYSIS - THE GROUP

		Q3	Jan - Sept.	
(Amounts in NOK 1.000)	2016	2015	2016	2015
Cash flow from operating activities:				
Profit after tax	-6 204	-4 713	-12 094	-9 230
Adjustment:				
Depreciation	555	698	1 529	2 050
Amortization	0	0	33	0
Employee stock options	555	367	1 351	367
Changes in working capital				
Inventory	592	1 476	-247	2 382
Account receivables and other receivables	-1 887	-2 228	-5 801	-9 450
Payables and other current liabilities	3 452	3 181	-1 381	-1 339
Net cash flow from operating activities	-2 937	-1 219	-16 610	-15 220
Cash flow from investing activities:				
Purchase of fixed assets	-54	-112	-58	-637
	-54 26	7	-56 59	-03 <i>1</i>
Change in long term receivables  Net cash flow from investing activities	-28 -	-105	<u>59</u> _	-596
net cash now from investing activities		-103	<u> </u>	-550
Cash flow from financing activities:				
Cashflow from private placement	0	0	0	4 475
Net cash flow from financing activities	0	0	0	4 475
Changes in cash and cash equivalents	-2 963	-1 324	-16 609	-11 343
Cash and cash equivalents at the beginning of period	64 697	78 265	78 343	88 283
Cash and cash equivalents at end of period	61 734	76 941	61 734	76 941



Notes to the interim accounts for 3rd quarter 2016

#### Note 1 - Basis of preparation of financial statements

These financial statements are the unaudited interim consolidated financial statements (hereafter "the Interim Financial Statements") of Biotec Pharmacon ASA and its subsidiaries (hereafter "the Group") for the period ended September 30 2016. The Interim Financial Statements are prepared in accordance with the Interim Accounting Standard 34 (IAS 34). These Interim Financial Statements should be read in conjunction with the Consolidated Financial Statements for the year, ended December 31 2015 (hereafter "the Annual Financial Statements"), as they provide an update of previously reported information.

The accounting policies used in the Interim Financial Statements are consistent with those used in the Annual Financial Statements. The presentation of the Interim Financial Statements is consistent with the Annual Financial Statements. Where necessary, the comparatives have been reclassified or extended from the previously reported Interim Financial Statements to take into account any presentational changes made in the Annual Financial Statements or in these Interim Financial Statements.

Income tax expense or benefit is recognized based upon the best estimate of the weighted average income tax rate expected for the full financial year. Deferred tax asset is accounted at NOK 0 in the balance sheet.

#### Note 2 - Analysis of operating revenue and -expenses, segment information

Services provided by the parent company are expensed at both segments according to agreements with actual subsidiary. Corporate overhead costs remain unallocated.

		Q3		Jan - Sept.		
(Amounts in NOK 1.000)	2016	2015	2016	2015		
Sales revenue:						
Beta-Glucans	15 119	11 020	31 760	19 931		
Enzymes	5 996	5 391	21 929	20 288		
Group operating sales revenues	21 115	16 411	53 689	40 219		
Gross profit			00 000			
Beta-Glucans	4 982	5 399	12 926	9 637		
Enzymes	5 844	4 787	21 557	19 151		
Group gross profit	10 826	10 186	34 482	28 788		
Other revenues						
Beta-Glucans	812	250	1 826	1 272		
Enzymes	572	1 452	3 153	4 230		
Unallocated revenues corporate level	0	2	0	3		
Group other revenues	1 384	1 704	4 979	5 504		
Operating expenses:						
Beta-Glucans	-9 510	-7 293	-27 061	-18 512		
Enzymes	-6 811	-6 008	-19 479	-17 228		
Unallocated corporate expenses	-1 772	-2 091	-3 873	-5 841		
Group operating expenses	-18 089	-15 392	-50 413	-41 581		
EBITDA						
Beta-Glucans	-3 715	-1 644	-12 310	-7 604		
Enzymes	-395	231	5 231	6 153		
Unallocated corporate expenses	-1 772	-2 089	-3 873	-5 838		
EBITDA	-5 883	-3 502	-10 952	-7 290		
Amortization:						
Beta-Glucans	-405	-439	-1 082	-1 290		
Enzymes	-136	-233	-405	-683		
Unallocated corporate expenses	-14	-25	-42	-77		
Group amortization	-555	-698	-1 529	-2 050		
EBIT						
Beta-Glucans	-4 120	-2 083	-13 392	-8 894		
Enzymes	-531	-2	4 826	5 470		
Unallocated corpoate expenses	-1 786	-2 115	-3 915	-5 915		
EBIT	-6 438	-4 200	-12 480	-9 340		

Oslo, October 25, 2016

The Board of Directors of Biotec Pharmacon ASA

Erik Thorsen Olav Flaten Inger Rydin Chairman Director Director

Richard Godfrey Masha Strømme Gerd Nilsen Svein W. F. Lien Director Director CEO