

# Board of Directors' Annual Report 2011

## 1. About Biotec Pharmacon ASA

Biotec Pharmacon ASA is a research-based industrial company that develops and delivers unique fine chemicals and solutions primarily from in-house R&D. The company's business is divided into two business segments:

- Beta-glucans for use in medical devices, as dietary supplements and as pharmaceutical product candidates
- Marine enzymes for use in molecular research and diagnostics

The business segment beta-glucans was demerged into a wholly owned subsidiary under the name Biotec BetaGlucans AS from the beginning of 2011, while the marine enzymes business segment is managed by the subsidiary ArcticZymes AS (formerly Biotec Marine Biochemicals AS). This leaves Biotec Pharmacon ASA as a holding company with overall management and support, while the operations are conducted in the two subsidiaries.

All operation, with the exception for the manufacturing, moved into new and more efficient premises in the Science Park of University of Tromsø at the beginning of the year. The already close collaboration with the University was then strengthened even further. The company's manufacturing facility is still located nearby in the Tromsø area.

A private placement in late 2010 and a subsequent repair share issue in early 2011 secured the company necessary financial strength throughout the year.

The company's goal for the beta-glucan operations in 2011 was establish the basis for a new advanced wound care product. The company demonstrated that it was able to formulate a stable and robust product with properties that are expected to be attractive to this market. The final product development started in the 2nd half of 2011.

The objectives for the enzyme activities were to strengthen the foundation for growth and launch new products into the market. The intensified marketing of ArcticZymes' products, achieved significant growth in customer numbers and expanded geographic distribution, which will form the basis for further growth in coming years, but it did not achieve an income in line with expectations for 2011.

In general the Board is pleased with the results achieved, with the exception of the weak revenue growth for the enzyme segment. An exclusivity clause relating to the sale of the company's largest product, shrimp alkaline phosphatase (SAP), led to stagnation and low sales in 2011. This has now been changed through a renegotiated agreement, and the Board expects to see a sales growth within this area in the future.

## 2. Beta-glucans

The business segment beta-glucans organized in the company Biotec BetaGlucans AS, is developing applications based on its proprietary soluble beta-1,3/1,6-glucan (SBG). This active substance is produced at the company's production facility in Tromsø in accordance with GMP (Good Manufacturing Practice). The immunomodulatory properties of this group of substances have shown to be promising in the treatment of several immune-related diseases, and the company now focuses on developing products for topical (skin) wounds. Furthermore, the company has projects in early stages in immunotherapy of cancer, oral mucositis and inflammatory bowel disease (IBD).

During 2011 the company has completed the formulation of a wound care product, which will be a gel in a tube. The product has been tested in several animal models and shows at least as good performance as the previous formulation and significantly better results than other commercially available hydrogels that have been tested. Stability programs for the new formulation have been ongoing since mid 2011 without signs of change. The company expects that this formulation will provide the basis for a robust and stable product.

The company has also done a great deal of efforts to clarify the optimal classification of the product as Medical Device. The potential partners are looking for a most unique product, which also involves looking at the most demanding classification. Such a choice is supported by the fact that the product is very well documented and has shown far better results in early studies than traditional hydrogels. It is therefore logical and desirable to distance the product from other hydrogels and thereby create added value for the company and its future partners.

The market for advanced wound care products is very attractive, and there is a strong interest for new advanced products. According to Espicon's analysis Europe represents about half of the world market for advanced biogels, a good starting point for a European company.

Throughout the year, the company has been in continuous dialogue with potential partners with the ambition to enter into one or more partner agreements. Talks with leading market players have developed positively, and we are now working to get a deal in place to ensure a good launch of the company's first product. Since the structure of such an agreement is of great strategic importance for the further development of the company, it has been the Board's and the administration's view that the company should spend the time needed to achieve the best possible deal, as long as this does not delay the company's commercial development.

Due to limited capacity within the company the projects in the treatment of oral mucositis, immunotherapy of cancer and the treatment of inflammatory bowel disease were not prioritized in 2011. The company has previously invested significantly in these areas, and extensive patent rights have been secured, giving the possibility to develop these areas at a later stage.

The company collaborates with Memorial Sloan-Kettering Cancer Center (MSKCC) in New York on the use of SBG in combination with antibody-based cancer treatment. During the year a final report from the early stage (I / II) clinical trial was completed, the MSKCC had tested proprietary cancer antibodies in combination with

beta-glucans from Biotec. The study showed good tolerance and encouraging effect in children affected by neuroblastoma.

The company's activities within dietary supplements and cosmetics were at the end of 2009 sold to Sana Pharma AS with an exclusive supply agreement of bulk product from the factory in Tromsø. Throughout the year there has been a very good working relationship with Sana Pharma, and revenues increased by 63% from NOK 4.3 million in 2010 to NOK 7.0 million in 2011.

### **3. Marine enzymes:**

The subsidiary ArcticZymes AS develops, markets and sells a increasing portfolio of cold adapted enzymes. These enzymes are particularly well suited for sample preparation before amplification of DNA and RNA samples. This is a major growth area in molecular biology, both for research purposes and routine diagnostics.

The company's enzymes are part of products (kits) from leading international companies and are used in both "*in vitro*" diagnostic (IVD; products for the diagnosis of diseases) and research products to market.

The unique properties of the enzymes are based on their origin from organisms that live in the cold Arctic Ocean. This means the enzymes are active at low temperatures, but they also have a thermal sensitivity that allows them to easily inactivate by heating. Use of competing enzymes usually involves time-consuming and costly extraction procedures, which often gives great loss of sample material and the risk of contamination. Many customers are working with very limited amounts of DNA or RNA, and it is a great advantage that loss from extraction and risk for contamination are minimized.

The company has good patent protection on its products. The company currently markets five unique enzymes from Arctic organisms. After the phasing out of natural (native) SAP, all enzymes are now recombinant (artificially manufactured in micro-organisms), and hence independent of access to biological materials.

The company's product portfolio includes:

- Shrimp Alkaline Phosphatase (SAP) - Alkaline phosphatase from shrimp
- Double-Strand Specific DNase (ds-DNase) from stress
- Heat-labile Double-Strand Specific DNase (HL-dsDNase) - proprietary mutant of dsDNase
- Cod Uracil-DNA Glycosylase (UNG Cod) - UNG from cod
- Salt Active nuclease (SAN) - general nuclease from a marine bacterial

Distribution of SAP, the company's largest product, has for years been made through an exclusive agreement with the U.S. company Affymetrix Inc. Sales of SAP to this customer did not develop according to expectations, and early in 2011 the company entered into a dialogue with Affymetrix to find solutions to the situation. In September, the company announced that the parties had entered into a new long-term non-exclusive agreement where Affymetrix also retain permission to use the SAP product in their own kits.

ArcticZymes are now building up an international sales organization and it was therefore strategically important also to be in control of the sales of the SAP

product. The company immediately began efforts to obtain new customers, but it is impossible to avoid a negative effect on sales performance in 2011. Revenue for SAP in 2011 was NOK 7.9 million, down from NOK 16.2 million in 2010.

Throughout the year the company had a very good growth for several of the other enzymes, especially Cod UNG has increased by 31% to \$ 5.8 million.

During the year the company has strengthened its focus on central Europe and established an office in the United States which also has an agreement with an incubator company that will provide support and logistics. Through the newly established subsidiary ArcticZymes Inc in the United States, ArcticZymes will strengthen its market development and customer support in this market.

Increased focus on direct sales and a new web shop has increased of sales directly to end users under ArcticZymes' own name. Although this volume is still small, it is important for the profiling of the company in the market. The company has also seen a gradual increase in sales to Asia and has received the first orders from Africa and the Middle East.

During the year ArcticZymes started several projects with major international companies, with the ambition to have its enzymes included in formulated solutions (new kits) under development. Such agreements provide good and stable earnings when the products are launched by these customers.

ArcticZymes also considers to launch products that contain more than just enzymes, which would be a natural development of the product portfolio and business in this area.

Sales of dsDNase developed positively in 2011, with increased sales to major players in the molecular biology market.

An improved version of dsDNase called HL-dsDNase and Salt active nuclease (SAN) was launched in 2010. Both of these supplements to the existing portfolio have shown good progress in 2011.

The company's active participation in the bioprospecting program MabCent is expected to lead to several interesting product candidates that are currently evaluated for possible development and commercialization. The collaboration with the University of Tromsø was further reinforced in 2010 with the purchase of the company Marimol AS which has the rights to the commercialization of enzymes from the MARZymes project. This is a 5-year project that has received significant research funding for bio-prospecting for enzymes in the Arctic. The company works closely with research groups in MARZymes to ensure that project activities are commercially relevant.

In addition, the enzyme activities are involved in activities on Svalbard through a collaborative project which explored for interesting enzymes in eukaryotic microorganisms (microalgae).

Generally ArcticZymes is well positioned to launch new unique cold active enzymes to the molecular biology market going forward.

#### **4. The parent company's activities**

The Group's operations are now placed in the subsidiaries Biotec BetaGlucans AS and AS ArcticZymes. The parent company's tasks include general administration and finance functions, patenting and quality function. Group CEO, Svein Lien is also responsible for the operational development within the business segment beta-glucans, while Managing Director Jan Buch Andersen in ArcticZymes AS has similar responsibilities for the enzyme activities.

The work to get the group ISO-certified according to the ISO 13485 standard started during the year. Final certification is expected to be achieved in 2012.

During 2011, it was submitted several new patent applications in the beta-glucan area that will lead to an extended protection both in topical wound care and in cancer.

#### **5. Net Earnings and Balance Sheet**

##### Profit and loss account

The Profit and Loss account for the Group Biotec Pharmacon has been prepared in accordance with International Financial Reporting Standards (IFRS). Biotec Pharmacon Group had sales of NOK 23.0 million in 2011, compared to NOK 25.9 million in 2010. The bulk of its revenue came from sales of products within the business area of marine enzymes, while the business segment beta-glucans currently sells products exclusively to Sana Pharma AS, which bought the former subsidiary Immunocorp Consumer Health AS in late 2009. Sales of marine enzymes fell 30% from the previous year due to a decrease in SAP sales under an exclusive sales agreement, while sales of beta-glucans to consumer health and cosmetics increased by 63% from 2010.

Net profit for the Group was NOK -20.1 million, compared with a profit of NOK -28.5 million in 2010. The group had in 2011 an operating profit (EBIT) for beta-glucan range of NOK -18.4 million, compared to NOK -34.9 million in 2010. The segment marine enzymes had an operating profit (loss) of NOK -2.8 million against a net profit of NOK 5.6 million for 2010. All costs in the group are allocated to these two business areas.

##### Cashflow

The Group had a cash flow from operating activities of NOK -10.8 million in 2011, compared to NOK -25.0 million in 2010. Cash flow from investing activities was NOK -4.6 million against NOK -1.4 Million in 2010. The group has invested during 2011 NOK 1.8 million in fixed assets and NOK 2.8 million in the development of new products prepared for sale. Net cash from financing activities was NOK 8.1 million in 2011, compared to NOK 20.1 million in 2010.

Cash flow from financing activities during 2010 and 2011 reflects primarily a share issue in December 2010, which was followed by a subsequent share offering in early 2011 and two additional minor placements directed at employees.

Net cash flow in 2011 was NOK -7.3 Million, compared to NOK -6.3 Million for 2010.

##### Balance

The equity of the Group amounted to NOK 45.8 million at the end of 2011, compared to NOK 36.4 million at the beginning of the year. The equity ratio was 81%. Liquid assets amounted to NOK 36.1 million as of 31.12.2011, compared to NOK 43.4 million previous year. The company holds no debt. The company has an unused overdraft facility with the bank at NOK 10.0 million.

### The parent company

Sales revenues for 2011 of the parent company Biotec Pharmacon ASA was NOK 8.6 million while other income amounted to NOK 124.9 million. Net income was NOK 110.9 million. Sales revenues are primarily intercompany sales of services to the subsidiaries, while other income comes from the sale of the business segment beta-glucans from the parent company to the wholly owned subsidiary Biotec BetaGlucans AS in February 2011. For 2010, revenues were NOK 6.9 million and profit of NOK -36.7 million. The Group's development in the beta-glucan area has until February 2011 taken place in the parent company Biotec Pharmacon ASA, which affects the comparison between 2011 and 2010. Deferred tax assets were entirely removed from the balance at the end of 2009. Currently, at 31.12.2011, the timing of future taxable profits is not predictable, and therefore one chooses not to enable the possible tax asset. This will be reassessed during 2012.

The Board proposes that the net profits of the parent company Biotec Pharmacon ASA at NOK 110.9 million is to cover previously uncovered losses of NOK 2.6 million and that the remainder of NOK 108.3 million is allocated to retained earnings. Parent company's distributable equity as of 31.12.2011 is NOK 108.3 million.

### The Group

The result for 2011 reflects the priorities of the Board that has been communicated to the stock market after the reorganization in early 2010. Research and development costs within the beta-glucan segment decreased in 2011 compared with the previous year. The enzyme segment built up their organization in both sales and R & D, which has resulted in higher costs compared with 2010. The total R & D costs for the group in 2011 was NOK 22.9 million compared to NOK 27.2 million in 2010.

The Board is not aware of any significant impact on the company's position beyond what is stated in the financial statements. After the end of 2011 and forward to the presentation of the annual report and accounts, no issues of significant importance not mentioned in the report have occurred.

The financial statements are prepared on the basis of a going concern. The basis for this assumption is the company's plans, the current capital position and long-term forecasts for the company.

## **6. Shareholder matters**

The company's stock price fell 32% through 2011, from NOK 7.64 to NOK 5.20 at year end.

Following the private placement at the end of 2010, the company completed in the first quarter of 2011 a subsequent offering of 1,200,000 shares at NOK 6.30, directed towards existing shareholders who had not been offered to participate in the private placement in December.

The Board wishes to stimulate the employees to become shareholders in the company. The employees received during the year an offer to buy shares at a discounted price within the current tax rules, which involves a set number of shares at a 20% discount limited to a taxable profit of NOK 1,500 per employee. This offer was used by 66% of the employees. All employees apart from CEO were in 2010 granted share options at NOK 6.17 until 1<sup>st</sup> April 2011. 214,906 shares were issued under this program, representing 97.2% of the allocation.

A new option program was introduced for all employees in 2011, except for the CEO who has a separate arrangement. The program includes 636,000 options and three-year period. The options may be exercised within one year from 1st April 2014, on specific dates. Strike price is set at NOK13.96 per share, which corresponds to the average closing price of the last 5 trading days prior to the allocation, plus an annual increase of 15%. It is set a cap on the maximum gain at NOK 40.00 per option. A total of 1,154,500 stock options associated with employees are outstanding in the company.

There were no other transactions with related parties in 2011.

At the date of this report the company has 28,552,816 shares registered.

## **7. Risk**

The Group is exposed to various types of financial and operational risks.

The main financial risks relate to the development in 2012 of sales in ArcticZymes. The company sees a positive effect of having secured the commercial rights to its main product, SAP, and is now working actively to enter into new agreements to expand the revenue base. However, it is difficult to estimate how quickly the expected revenue growth will come, and how strong it will be, although the outlook is good.

Within the beta-glucans operation, the company has announced that it is in discussions with several potential partners for its first product for topical wound care. Even if these dialogues are positive, there are no guarantees that this work will lead to commercial agreements which can ensure a successful launch and a good sales development.

The company saw a positive development of beta-glucan sales for dietary supplements and cosmetics in 2011, and has received positive signals that this development will continue. As the company has sold the exclusive rights to market its beta-glucans in these segments, it is dependent on the success of this customer for future growth.

The group seeks to protect its intellectual property rights through patent filings. There will still be a risk that other companies may deny such rights. Similarly, the group may have to take on the costs to defend its rights against patent infringement by other companies.

A number of key personnel are central to the success of the company's operations. These key individuals are involved in the development of products, technologies, production processes and quality control, purchasing and marketing, and other activities of the company. The company is also dependent on recruiting

new qualified personnel. There is no guarantee that the company will be able to retain key personnel or be able to recruit key personnel in the future.

The company is dependent on certain key suppliers to manufacture products. The raw material for production of beta-1,3 / 1,6-glucan is delivered by a key supplier. The company may, if necessary, change suppliers over time, but cannot exclude that such changes could have a temporary negative impact on the company's operations.

Much of the company's revenues are in USD and Euro, while most costs are in Norwegian kroner. A higher exchange rate for USD and Euro against the Norwegian krone will affect the outcome in a positive direction, while lower rates will have the opposite effect. The Group's exposure will in longer term be changed by new product launches which will provide a different currency mix.

The Group holds no interest bearing debt. Financial investments are made only in the form of bank deposits, certificates or bonds with short maturities. The group is thus little exposed to interest rate risk. There are not taken risks in the stock market. The Group has no significant credit risks, and there were no records of bad debt I 2011.

The Board considers the financial status to be satisfactory given the current development in cash flow from operations and investing activities, together with plans and budgets for the coming period. The Board and administration will continue their efforts to strengthen financial flexibility of the Group further.

## **8. Working Environment and Staff**

At the end of 2011 there were 33 full- and part-time employees. There were 9 employees in the parent company Biotec Pharmacon ASA, 9 in Biotec BetaGlucans AS, and 15 employees in ArcticZymes AS. This is an increase of 4 employees during the year.

During 2011, employees were away from work 182 days due to sickness, which was unchanged at 2.9% compared with 2010. This low level reflects an environment that is generally regarded as good. It has not been initiated special measures during the year that affect the working environment. There were no serious accidents resulting in injury or material damage during the year.

The company moved its administration and R & D into new premises in the Tromsø Science Park in February 2011.

The company is committed to facilitating the recruitment and development of employees of both sexes. Gender equality is practiced as women and men are valued equally with regard to career opportunities and remuneration. At year end there were 15 women and 18 men employed by the Group. In management positions, there were 3 women and 10 men. The Board consists of 6 people, 2 of the 5 shareholder-elected representatives are women. The representative of the employees is a man.

## **9. Natural Environment**

The company's activities have little impact on the natural environment. Excipients and chemicals that cannot be recycled in the production process are collected and returned to an approved manufacturer for environmentally sound recycling. It is also established procedures for collecting various types of waste from laboratories and

separation of waste by source from other operations. The energy consumption during production is modest.

## **10. Principles of corporate governance**

The Board has established principles of corporate governance in line with the Accounting Act § 3-3. A more detailed statement about these principles is available on the company website [www.biotec.no](http://www.biotec.no).

## **11. Outlook**

The company has established a good foundation for further growth within its two business areas, which will form the basis for the business going forward. For the beta-glucan segment the main focus will be topical wound care. The short-term goal of this work is to complete product development, seek approval of the product as medical device, and establish a strong commercialization through partnership agreement (s).

The company will further clarify realistic objectives for further development of other applications for its beta-glucans, either alone or in partnership with others.

The general market opportunities and the expected growth in demand for enzymes products make it attractive to continue strengthening the resources in sales and marketing. The company anticipates rise in sales of enzyme products, but realizes that it may take some time to compensate for the reduced income from the largest customer for the SAP product.

The company expects continued high activity within research and development in both segments. It is expected that the Group will be certified according to ISO 13485 during 2012.

Overall, the Board believes that the work and the results achieved in 2011 represents a good basis for future growth and development in shareholder value going forward.

The Board thanks all employees for their efforts in 2011.

Tromsø, 29 March 2012

Board of Directors

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