Interim Report

First quarter 2016, BioPorto Group

May 4, 2016

Announcement no. 11

BioPorto®

BioPorto A/S CVR DK-17500317

Highlights

Distribution agreement with Siemens Healthcare and continued preparations for roll-out in the USA

In early January 2016, the subsidiary BioPorto Inc. was established in the USA and BioPorto hired the first key employees to the US organization. In preparation to the awaited FDA approval of The NGAL Test™, the new organization has initiated a dialogue with a number of selected hospitals and clinics in the USA regarding the use of The NGAL Test™ for research use.

BioPorto has submitted a reply to the FDA's questions in response to the company's application for approval of The NGAL Test™ for clinical use in the USA. Approval is expected to be achieved in time for the planned launch of the test in the US in Q2 2016.

In the beginning of January 2016, BioPorto entered a distribution agreement with Siemens Healthcare under which BioPorto is to provide an NGAL test adapted for Siemens Healthcare BN II and BN ProSpec Systems. The agreement is expected to have economic effect from the second half of 2016.

An article by BioPorto's European Advisory Board chaired by Prof. Dr. Jean-Louis Vincent on the suggested use of NGAL in clinical practice, specifically in cardiac surgical procedures, has been accepted into the prestigious American journal The Journal of Thoracic and Cardiovascular Surgery. The publication is an important recognition of NGAL as a biomarker of acute kidney injury (AKI) and is estimated to have profound implications for the global acceptance and implementation of The NGAL Test™.

The cooperation with the local distributor on the implementation of The NGAL Test™ in South Korea continues. In the first quarter, new users have been added. However, this has no direct impact on BioPorto's turnover in the first quarter, as the distributor's next order is expected to land in the second quarter of 2016.

Sales growth of 26% and increased costs related to US preparations

BioPorto generated first quarter revenue of DKK 5.2 million compared to DKK 4.1 million in the year-earlier period, corresponding to a growth of 26%. This growth is primarily related to a significant growth in the sales of antibodies, which is up by 51% in the first quarter of 2016 compared to last year. In the first quarter of 2016, the NGAL product portfolio generated revenue of DKK 1.6 million compared to DKK 1.5 million in 2015, of which DKK 0.9 million relates to The NGAL Test™ compared to DKK 0.8 million the previous year.

EBIT amounted to DKK -5.4 million in the first quarter of 2016 compared to DKK -4.4 million the previous year. Costs are higher as the result of the establishment of the US subsidiary, increased sales and marketing costs, and the strengthening of the organization. Furthermore, in the first quarter of 2016 additional trials for the FDA application have been conducted.

Guidance for 2016 maintained

Revenue is expected to be DKK 27-30 million in 2016, representing an increase of approximately 30-50%.

EBIT for 2016 is forecast at a loss between DKK 11-13 million. This is an adjustment from an EBIT loss of DKK 7-9 million in connection with the grant of warrants on April 8, 2016, based on an expected accounting impact of DKK -3.8 million.

Peter M. Eriksen, CEO comments: "In the first quarter, we have delivered solid sales growth across product areas, which I am very pleased with. We continue to execute on our strategic objectives, including our preparations for the launch of The NGAL Test™ in the USA, and we have recently submitted answers to the FDA's questions, meaning we are a step further in the process of approval. The level of activity and investment in the United States is reflected in higher costs, but we are within budget. As announced, we expect the most part of the growth to materialize in the second half of 2016, following an FDA approval and effect of the Siemens collaboration. "

Investor meeting

In connection with the release of the first quarter results, BioPorto hosts an investor meeting on May 4, 2016 at 3 pm. Please note that the meeting is held at Radisson Blu Scandinavia, Margrethepladsen 1 in Aarhus. Please sign up at investor@bioporto.com.

Financial highlights

	2016 3 months DKK thou- sand	2015 3 months DKK thou- sand	2015 12 months DKK thou- sand
Revenue	5,183	4,129	20,383
Operating profit/loss (EBIT)	(5,447)	(4,427)	(12,759)
Net financials	(93)	(60)	(255)
Operating profit/loss before tax	(5,540)	(4,487)	(13,014)
Profit/loss for the period	(5,086)	(3,977)	(10,732)
Comprehensive income	(5,050)	(3,977)	(10,732)
Non-current assets	1,957	1,419	1,676
Current assets	42,106	31,394	47,317
Total assets	44,063	32,813	48,993
Share capital	129,599	117,874	129,599
Equity	39,320	24,709	44,485
Non-current liabilities	58	80	64
Current liabilities	4,685	8,024	4,444
Total equity and liabilities	44,063	32,813	48,993
Cash flows from operating activities	(4,702)	(3,410)	(16,574)
Cash flows from investing activities, net	(487)	(33)	(517)
Of which investment in property, plant and equipment	(157)	0	(50)
Cash flows from financing activities	(5)	(5)	26,511
Total cash flows	(5,194)	(3,448)	9,420
Revenue growth	26%	-13%	9%
Gross margin	75%	65%	76%
EBIT margin	-105%	-107%	-63%
Equity ratio (solvency)	89%	75%	91%
Return on equity	-12%	-15%	-29%
Average number of employees	26	26	22
Average number of shares (1,000)	129,586	117,874	121,652
Earnings per share (EPS), DKK	(0.04)	(0.03)	(0.09)
Net asset value per share, year-end, DKK	0.30	0.21	0.34
Share price, period-end, DKK	4.66	1.67	4.82

Management review

Preparations for US roll-out continues

BioPorto has continued the implementation of its targeted US strategy of establishing a US business platform with sales and support functions. The organization currently consists of three key employees, and during the year an expansion to a total of 5-7 employees is expected. Sales efforts are aimed at established contacts and building new relationships among 20-30 hospitals and clinics, which the company has identified as the first target. Up until the FDA approval, these targets can use the test for research use and testing.

FDA approval of The NGAL Test™ pending

In March, BioPorto submitted a reply to the FDA as part of the application process for the approval of The NGAL Test™. The submission of answers is based on a number of questions received from the FDA at the end of December 2015. In BioPorto's view, the questions received from FDA are of a customary nature, and the reply is primarily based on additional clinical studies and extensive statistical treatment of the data already collected, which has affected costs in the first quarter of 2016. Approval is expected to be achieved in time for the planned launch of the test in the US in Q2 2016.

Additional users in South Korea and strategic use of *white paper*

The cooperation with the local distributor on the implementation of The NGAL Test™ in South Korea continues. In the first quarter, new users have been added. However, this has no direct impact on BioPorto's turnover in the first quarter, as the distributor's next order is expected to land in the second quarter of 2016. The cooperation is focused on implementing the NGAL Test™ and extending the use, eg from specialized departments to a more general application.

The sales of The NGAL Test™ and the addition of new users in Europe is relatively slow. Long decision processes and different incentive structures in European healthcare means a slower European uptake of The NGAL Test™ and the new diagnostic technology, leading to limited sales in the region. The white paper publication in *The Journal of Thoracic and Cardiovascular Surgery* on clinical use of NGAL, published in February 2016, however, has been met with interest and attention from both authorities and professionals in the health care community. It may therefore be instrumental in speeding up the process, as with NICE, the regulatory authority that sets the clinical guidelines in England, who are currently assessing NGAL as a marker for acute kidney injury. As previously stated, the uptake of The NGAL Test ™ in Europe is not expected to accelerate until the use of the test has been recognized and is widespread in the US.

Distribution agreement entered into with Siemens Healthcare

In January 2016, BioPorto and Siemens Healthcare entered into an exclusive, global distribution agreement whereby BioPorto will deliver an NGAL test adapted to selected Siemens Healthcare systems (BN II and BN ProSpec). As part of the agreement, Siemens Healthcare and BioPorto will collaborate on commercializing the adapted NGAL test as soon as it is ready for the systems. The agreement is deemed to be strategically important for the accessibility of NGAL tests and the awareness of NGAL as a diagnostic marker and it is expected to help generate revenue in the second half of 2016.

Strong increase in antibody sales and breakthrough in new customer segment

Sales of antibodies has increased significantly in the first quarter to DKK 2.9 million, which is 51% higher than same period in 2015. The increase is due to sales of large quantities of antibodies to assay developers, ie companies that produce their own assays based on BioPorto's antibodies. This segment has been a focus area for some time, and is expected to be an important part of sales going forward.

Financial review

Revenue

BioPorto generated first quarter revenue of DKK 5.2 million compared to DKK 4.1 million in the year-earlier period, corresponding to a growth of 26%. This growth is primarily related to a significant growth in the sales of antibodies, which is up by 51% in the first quarter of 2016 compared to last year. In the first quarter of 2016, the NGAL product portfolio generated revenue of DKK 1.6 million compared to DKK 1.5 million in 2015, of which DKK 0.9 million relates to The NGAL Test™ compared to DKK 0.8 million the previous year.

Figure 1. Revenue by quarter (DKKm)

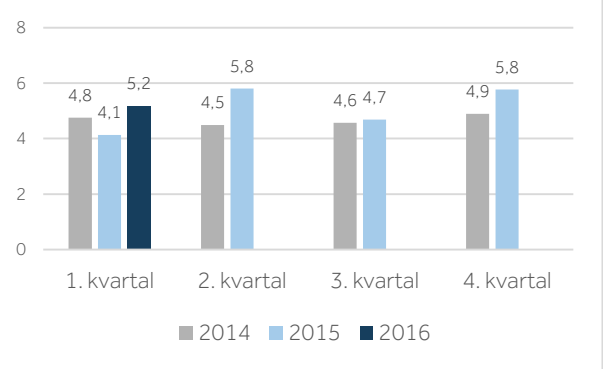
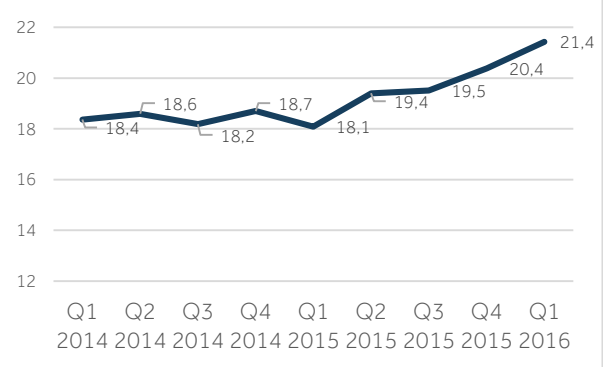


Figure 2. Revenue, LTM (DKKm)



Operating costs and operating results

In the first three months of 2016, production costs totaled DKK 1.3 million, which translates into a gross profit of DKK 3.9 million and a gross margin of 75%. This is a decent improvement over the same period in 2015, in which gross margin was 65%.

Capacity costs in the first quarter of 2016 amount to DKK 9.3 million compared to DKK 7.1 million last year. Costs are higher as the result of the establishment of the US subsidiary, increased sales and marketing costs, and the strenghtening of the organization, including the hiring of a COO and CFO as of January 1, 2016. Furthermore, in the first quarter of 2016 additional trials for the FDA application regarding The NGAL Test™ have been conducted, adding to the research and development costs.

This brought BioPorto's operating profit/loss before interest and tax (EBIT) amounted to DKK -5.4 million in the first quarter of 2016 compared to DKK -4.4 million the previous year.

Profit/loss before and after tax

Net financials in the first quarter of 2016 were an expense of DKK 57,000. The expenses are predominantly currency adjustments. Pre-tax loss for the first quarter of 2016 is thus DKK 5.5 million compared to a loss of DKK 4.5 million in the first quarter of 2016.

After income recognition of tax of DKK 454,000 in the period, the net profit for the period amounts to a loss of DKK 5.1 million compared to a loss of DKK 4.0 million last year.

Balance sheet

At the end of March 2016, BioPorto's blanace sheet totaled DKK 44.1 million. Long-term assets totaled DKK 2.0 million, which is an increase of DKK 0.3 million compared to December 31, 2015. The increase is due to investment in new lab equipment and the continued development of a new US-based antibody webshop.

Inventories and receivables amounted to DKK 12.4 million at the end of March 2016, which is on par with the amount at December 31, 2015. The cash position was DKK 29.7 million at March 31, 2016.

At the end of March 2016, equity amounted to DKK 39.3 million compared to DKK 44.5 million at the beginning of the year. Liabilities at March 31, 2016 totaled DKK 4.7 million and consisting primarily of trade payables and other debt.

Cash flow statement

Cash flows generated by operating activity were DKK – 4.7 million in the first quarter of 2016 (Q1 2015: DKK –3.4 million). Investments in the period amounted to DKK 0.5 million and cash flows generated by financing activities were DKK 0.0 mio. The cash flows for the period thus ended up at DKK -5.2 million compared to DKK -3.4 million in first quarter of 2015.

Significant events after the end of the period

After the end of the period, The Board of directors of BioPorto decided to establish a warrant program and to issue a total of 6,368,696 warrants to BioPorto's management and certain employees. With regard to approximately 50 % of the warrants, conditions for cancellation of all or part of the warrants apply in case the company does not achieve the announced revenue expectations for the coming years. In connection with the warrant program, the Company has also decided to offer selected senior members of BioPorto's American organization share-based incentive payment. The accounting impact of the grant of warrants and the share-based incentive payment is expected to amount to DKK -3.8 million at EBIT level in 2016.

Accounting policies

The interim report is presented in accordance with the accounting policies applied in the Group's annual report for 2015 and the following additions:

Foreign currency translation

Income statements of subsidiaries with a functional currency other than the Group's presentation currency are translated into the Group presentation currency at the year's weighted average exchange rate, and the balance sheets are translated at the exchange rate at the balance sheet date.

Exchange differences on translation of foreign subsidiaries' equity at the beginning of the year and exchange rate differences, arising from foreign subsidiaries' income statements are translated at average exchange rates, are shown as other comprehensive income and currency translation adjustments in equity.

Focus on sales and establishment in the US

The management priorities for the remaining part of 2016 comprise:

- FDA approval of NGAL
- US roll-out of The NGAL Test™ in Q2 2016 and implementation at 20 hospitals.
- Establishment of advisory board in the US
- Continued growth of NGAL in South Korea and moderate growth in the European market
- Launch of new immunodeficiency ELISA kits
- Enlarge the antibody portfolio

Guidance for 2016 maintained

Revenue is expected to be DKK 27-30 million in 2016, representing an increase of approximately 30-50%. This growth must primarily be generated by significantly accelerating sales of The NGAL Test™, while the new focus of sales aimed at the US and South Korea creates new routine users. A significant element will therefore be the US launch which, together with the distribution agreement with Siemens and the launch of new products, is expected to prompt a sharp increase in the last half of 2016.

Based on an expected accounting impact in connection with the grant of warrants on April 8, 2016, EBIT for 2016 is forecast at a loss between DKK 11-13 million. This is an adjustement from an EBIT loss of DKK 7-9 million. Profit after tax is also adjusted from a loss of DKK 5.5-7.5 million to a loss of DKK 9.5 to 11.5 million.

Forward-looking statements

This interim report contains forward-looking statements, including forecasts of future revenue and net profit/loss. Such statements are subject to risks and uncertainties, as various factors, many of which are beyond BioPorto's control, may cause actual results and performance to differ materially from the forecasts made in this interim report

For further information, please contact:

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About BioPorto
BioPorto Diagnostics A/S is an in-vitro diagnostics company that provides healthcare professionals in clinical and research settings with a range of diagnostic tests and antibodies. Our pioneering product portfolio includes assays for underdiagnosed diseases, including our NGAL tests for acute kidney injury. BioPorto is headquartered in Copenhagen, Denmark and is listed on the Nasdaq Copenhagen stock exchange.

Statement by the management

The Board of Directors and the Management Board today considered and approved the interim report of the BioPorto Group for the period January 1, 2016 – March 31, 2016.

The interim report, which is unaudited and has not been reviewed by the company's auditors, is presented in accordance with IAS 34 "Interim financial reporting" as adopted by the EU and additional Danish disclosure requirements for interim reports of listed companies.

In our opinion, the interim report gives a true and fair view of the Group's assets, liabilities and financial position at March 31, 2016 and of the results of the Group's operations and cash flows for the period January 1, 2016 – March 31, 2016.

Furthermore, in our opinion the management's report includes a fair review of the development and performance of the business, the results for the period and the Group's financial position in general and describes the principal risks and uncertainties that it faces.

Hellerup, May 4, 2016

Management board:

_____
Peter Mørch Eriksen
CEO

Board of Directors:

_____
Thomas Magnussen
Chairman

_____
Torben A. Nielsen
Vice chairman

_____
Jan Kuhlmann Andersen

_____
Niels Christian Nielsen

Statement of comprehensive income (condensed)

Income statement

	2016 3 months DKK thousand	2015 3 months DKK thousand	2015 12 months DKK thousand
Revenue	5,183	4,129	20,383
Gross profit/loss	**3,884**	2,695	15,481
Profit/loss before financial items (EBIT)	**(5,447)**	**(4,427)**	**(12,759)**
Profit/loss before tax	**(5,540)**	**(4,487)**	**(13,014)**
Profit/loss for the period	**(5,086)**	**(3,977)**	**(10,732)**
	DKK		DKK
Profit/loss / comprehensive income per share (EPS & DEPS)	(0.04)	(0.03)	(0.09)

Statement of comprehensive income

	2016 3 months DKK thousand	2015 3 months DKK thousand	2015 12 months DKK thousand
Profit/loss for the period	**(5.086)**	**(3.977)**	**(10.732)**
Exchange rate adjustment foreign subsidiaries	36	0	0
Comprehensive income	**(5.050)**	**(3.977)**	**(10.732)**

Balance sheet

ASSETS	2016 31 March DKK thou- sand	2015 31 March DKK thou- sand	2015 31 December DKK thou- sand
Non-current assets			
Property, plant and equipment and intangible assets			
Fixtures and fittings, tools and equipment	563	596	451
Rights and software	704	176	559
Total financial assets	690	647	666
Total non-current assets	**1,957**	**1,419**	**1,676**
Current assets			
Total inventories and receivables	12,434	9,395	12,450
Cash	29,673	21,999	34,867
Total current assets	**42,106**	**31,394**	**47,317**
TOTAL ASSETS	**44,063**	**32,813**	**48,993**

Balance sheet

LIABILITIES	2016 31 March DKK thou-sand	2015 31 March DKK thou-sand	2015 31 December DKK thou-sand
Equity			
Share capital	129,599	117,874	129,599
Share-based payments	568	648	568
Treasury shares	0	0	0
Retained earnings	(90,847)	(93,813)	(85,682)
Total equity	**39,320**	**24,709**	**44,485**
Liabilities			
Non-current liabilities			
Lease obligation	58	80	64
Non-current liabilities	**58**	**80**	**64**
Current liabilities			
Current portion of non-current liabilities	22	20	22
Trade payables	1,004	455	1,227
Other payables	3,658	7,549	3,195
Current liabilities	**4,685**	**8,024**	**4,444**
Total liabilities	**4,743**	**8,104**	**4,508**
TOTAL LIABILITIES	**44,063**	**32,813**	**48,993**

Statement of changes in equity

	Share capital DKK thousand	Treasury shares DKK thousand	Share-based payments DKK thousand	Retained earnings DKK thousand	Total DKK thousand
Equity 1 January 2016	129,599	0	568	(85,682)	**44,485**
Comprehensive income	0	0	0	(5,050)	**(5,050)**
Other changes in equity	0	0	0	(115)	**(115)**
Equity at 31 March 2016	**129,599**	**0**	**568**	**(90,847)**	**39,320**

	Share capital DKK thousand	Treasury shares DKK thousand	Share-based payments DKK thousand	Retained earnings DKK thousand	Total DKK thousand
Equity 1 January 2015	117,874	0	648	(89,836)	**28,686**
Profit/loss for the year/ comprehensive income	0	0	0	(3,977)	**(3,977)**
Equity at 31 March 2015	**117,874**	**0**	**648**	**(93,813)**	**24,709**

Cash flow statement

	2016 3 months DKK thou- sand	2015 3 months DKK thou- sand	2015 12 months DKK thou- sand
Profit/loss before financial items	(5,447)	(4,427)	(12,759)
Amortisation, depreciation and impairment losses	90	70	300
Cash generated from operations before working capital	**(5,357)**	**(4,357)**	**(12,459)**
Changes in working capital	710	1,008	(6,012)
Cash generated from operations	**(4,647)**	**(3,349)**	**(18,471)**
Financial income, received	65	47	308
Financial expenses, paid	(120)	(108)	(564)
Tax refund	0		2,153
Cash flows from operating activities	**(4,702)**	**(3,410)**	**(16,574)**
Purchase of operating equipment	(157)	0	(50)
Purchase of rights and software	(190)	(33)	(464)
Purchase of financial assets	(140)	0	(21)
Sale of operating equipment	0	0	18
Cash flows from investing activities	**(487)**	**(33)**	**(517)**
Capital increases	0	0	26,531
Reduction of lease obligation	(5)	(5)	(20)
Cash flows from financing activities	**(5)**	**(5)**	**26,511**
Net cash flow from operating, investing and financing activities	**(5,194)**	**(3,448)**	**9,420**
Cash and cash equivalents at 1 January	34,867	25,447	25,447
Cash and cash equivalents at 31 December	**29,673**	**21,999**	**34,867**

Segments

GEOGRAPHIC DISTRIBUTION:	2016 3 months DKK thou-sand	2015 3 months DKK thou-sand	2015 12 months DKK thou-sand
Denmark	366	225	1,783
Rest of Europe	2,331	1,904	7,195
North America	1,993	1,532	7,634
Asia	339	411	2,448
Other countries	154	57	1,323
Revenue	**5,183**	**4,129**	**20,383**

PRODUCT GROUPS	2016 3 months DKK thou-sand	2015 3 months DKK thou-sand	2015 12 months DKK thou-sand
The NGAL test	876	752	3,747
ELISA Human NGAL kits	500	442	2,554
ELISA Animal NGAL kits	270	282	920
ELISA MBL kits	343	464	2,530
Antibodies*	2,942	1,948	9,489
Other products and licenses	252	241	1,143
Revenue	**5,183**	**4,129**	**20,383**

* In Q1 2016, public innovation assistance of DKK 283 thousand relating to the development and production of a new antibody is included as revenue (Q1 2015: DKK 0 thousand and Q1-Q4 2015: DKK 1.075 DKK thousand).