Interim Report

First quarter 2017, BioPorto Group

May 4, 2017

Announcement no. 09

BioPorto®

BioPorto A/S CVR DK-17500317

Highlights

US clinical trials for The NGAL Test™ initiated and sales of the test has grown 42%

In early 2017, following three months of dialog with the authorities, BioPorto finalized the protocol that forms the basis for the regulatory submission of The NGAL Test™ to the Federal Drug Administration (FDA) in the US. The important step was in alignment with the new submission strategy, which was initiated in Summer 2016.

After finalizing the protocol, BioPorto has initiated the clinical trials to generate the data that will support the FDA application for The NGAL Test™. Clinical trials will be conducted at approximately 20 clinics and hospitals in the US and will involve the recruitment of 530 patients, the first of which was enrolled in the beginning of April 2017.

In cooperation with Siemens, a customized NGAL test was tested and approved for use on the Siemens BN Platforms in February 2017 and launched internally by Siemens in April 2017. This was in accordance with the exclusive, global distribution agreement which was entered into in 2016 between the parties. Siemens has placed their first order and has commenced distribution of the NGAL product.

Sales performance for The NGAL Test™ has grown 42% in first quarter of 2017, driven by a sharp growth of 173% to US clients using the test for Research Use Only purposes, and a 20% growth in the rest of the world, primarily driven by sales to Siemens.

Sales growth of 11% and increased activities related to FDA approval process

BioPorto generated first quarter revenue 2017 of DKK 5.7 million compared to DKK 5.2 million last year, corresponding to a year-over-year growth of 11%. This growth is primarily related to the uptake in sales of The NGAL Test™, but is also positively impacted by the performance of antibody sales and ELISA kits. In the first quarter of 2017, The NGAL Test™ generated revenue of DKK 1.2 million, which is 42% higher than sales in the first quarter of 2016.

In first quarter 2017 BioPorto's operating loss before interest and tax (EBIT) amounted to DKK 9.3 million compared to a loss of DKK 5.4 million the previous year. Costs have increased substantially due to higher spending on items related to the FDA approval process, establishing a subsidiary in the US in Q1 2016 and introduction of a warrant program. The restructuring effort which BioPorto initiated in the fall of 2016 is still being implemented and will reduce capacity cost by DKK 3.0 million in 2017 and DKK 4.0 million in 2018, once all initiatives are fully implemented.

Guidance for 2017 maintained

Revenue in 2017 is expected to be DKK 25-28 million, equivalent to a growth rate of 20-35%.

EBIT forecast for the financial year 2017 is a loss between DKK 26-29 million, including non-liquidity constraining cost for a recently established warrant program.

Peter M. Eriksen, CEO comments: "In the beginning of 2017, we successfully executed on our new FDA submission plan by completing the pre-submission document and recruiting the first patient into the clinical study for The NGAL Test™ in the US. Furthermore, and very importantly, we have had a strong uptake in the sales of The NGAL Test™, primarily driven by very strong growth in Research Use Only sales in the US, but also a solid increase in the rest of the world. We are well on our way to reaching important strategic milestones set out for 2017, which will bring us closer to the goal of an FDA approval for The NGAL Test™ in 2018, and hence realizing the future value-creation potential of BioPorto."

Investor meeting

In connection with the release of the first quarter results, BioPorto will host an investor meeting on May 4, 2017 at 3 pm. The meeting will be held at Hedeager 2, 8200 Aarhus N, plan 1, north wing, room 22-26. To attend the meeting, please sign up at investor@bioporto.com.

Financial highlights

	2017 3 months DKK thousand	2016 3 months DKK thousand	2016 12 months DKK thousand
Revenue	5,743	5,183	20,720
Operating profit/loss (EBIT)	(9,287)	(5,447)	(25,047)
Net financials	(137)	(93)	148
Operating profit/loss before tax	(9,424)	(5,540)	(24,899)
Profit/loss for the period	(8,549)	(5,086)	(22,800)
Total comprehensive income	(8,569)	(5,050)	(23,113)
Non-current assets	2,954	1,957	3,069
Current assets (excl. Cash)	13,692	12,433	11,931
Cash	29,214	29,673	35,641
Total assets	45,860	44,063	50,641
Share capital	142,494	129,599	142,494
Equity	36,367	39,320	44,291
Non-current liabilities	1,198	58	1,204
Current liabilities	8,295	4,685	5,146
Total equity and liabilities	45,860	44,063	50,641
Cash flows from operating activities	(6,410)	(4,817)	(19,660)
Cash flows from investing activities, net	(12)	(372)	(401)
Of which investment in property, plant and equipment	(12)	(157)	(157)
Cash flows from financing activities	(5)	(5)	20,836
Total cash flows	(6,427)	(5,194)	774
Revenue growth	11%	26%	2%
Gross margin	72%	75%	76%
EBIT margin	-162%	-105%	-121%
Equity ratio (solvency)	79%	89%	87%
Return on equity	-21%	-12%	-51%
Average number of employees	25	26	27
Average number of shares (1,000)	142,494	129,586	131,025
Earnings per share (EPS), DKK	(0.06)	(0.04)	(0.17)
Net asset value per share, year-end, DKK	0.26	0.30	0.31
Share price, period-end, DKK	2.39	4.66	2.10

Management review

Finalization of new protocol for clinical trials for regulatory approval of The NGAL Test™ in the US

In October 2016 BioPorto presented a new pre-submission document to the FDA, incorporating a new clinical trial for obtaining data to submit for regulatory approval of The NGAL Test™ for clinical use in the US. Based on feedback obtained from the FDA and subsequent discussions with FDA representatives, BioPorto in January 2017 finalized the protocol that forms the basis for the regulatory approval submission for the test in the US. Following submission of the application to FDA, an approval is expected in mid-2018, assuming a normal review process.

The external cost of implementing the registration process in 2017 and 2018 are expected to be DKK 17–18 million, in addition to the approximately DKK 3 million that BioPorto spent on the process in 2016.

Preparation of clinical trials and first patient recruitment

In the first quarter 2017, BioPorto identified the hospitals that will conduct the clinical trials. Interest has been strong and BioPorto will enter into agreements with approximately 20 hospitals, which will recruit the 530 patients that will be enrolled as part of the clinical study supporting the FDA application for The NGAL Test™. Among the participating hospitals are Cleveland Clinic, Huston Methodist Hospital, Massachusetts General Hospital and The Brigham& Women's Hospital which are among the leading clinics in the US.

On schedule and in line with the overall process plan for the FDA approval, the study was officially commenced in the beginning of April 2017 when the first patients were recruited. Over the course of the coming months recruitment will be intensified. Last patient enrollment is currently expected to happen at the end of 2017 or beginning of 2018.

Distribution agreement with Siemens enters new phase

In 2016 BioPorto entered into an exclusive, global distribution agreement with Siemens. BioPorto will deliver a customized NGAL test for use on Siemens BN II and BN ProSpec Systems. The customized NGAL test was tested and approved for final use on Siemens BN Systems in January 2017. Subsequently, Siemens has placed their first order and will now distribute the NGAL test thereby increasing order volume and positively impacting BioPorto's financial performance.

Strong growth in sales of The NGAL Test™ and the interest for NGAL

First quarter 2017 has exhibited strong performance in the sales of The NGAL Test™. Overall, revenue from The NGAL Test™ in the first three months of 2017 was DKK 1.2 million compared to DKK 0.9 million in the same period last year, corresponding to a growth of 42%.

While growth in the non-US market fueled by sales to Siemens increased a very healthy 20% year-over-year, performance was particular strong in the US market, where The NGAL Test™ was sold to Research Use Only clients. A growth of 173% in North America is an important indicator that NGAL is gaining momentum and that BioPorto's cultivation of the market with its local organization is creating solid results. The progress in US sales of the test is driven by both increased repeat sales and the addition of new hospitals and clinics to the customer list. In total, 12 clinics and hospitals are now regular users of The NGAL Test™ in the US.

The development and positive dialogue regarding the test in the US has also revealed a strong interest from professionals and clinicians in exploring opportunities for the use of NGAL as a biomarker in other indications such as inflammation, oncology and for use within veterinarian medicine. Areas that could provide further opportunities for BioPorto going forward.

Going forward, BioPorto will increase its focus on European sales, and as such has taken on direct sales of The NGAL Test™ in two major European markets rather than rely on distribution partners.

Sales of antibodies and ELISA kits up

Sales of antibodies has increased in the first quarter to DKK ™ 3.1 million from DKK 2.9 million last year – a growth of 6%. The increase comes on top of strong performance last year, where the focus on sales of large quantities of antibodies to assay developers, (i.e. companies that produce their own assays based on BioPorto's antibodies), kicked influenced the strategic decision to focus further on bulk order sales.

Financial review

Revenue

BioPorto generated first quarter revenue of DKK 5.7 million compared to DKK 5.2 million last year, corresponding to a year-over-year growth of 11%. This growth is primarily related to the uptake in sales of The NGAL Test™, which is up 42%, but is also positively impacted by the performance in antibody sales (+6%) and ELISA kits (+12%).

Figure 1. Revenue by quarter (DKKm)

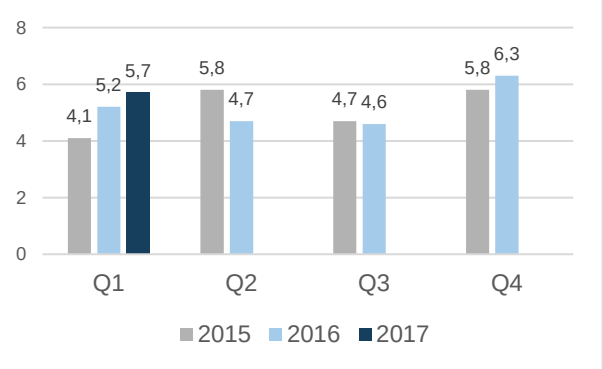
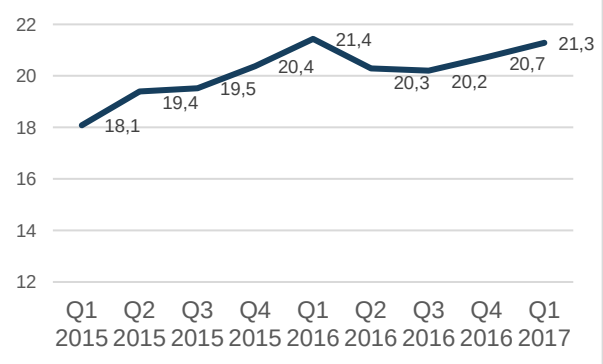


Figure 2. Revenue, LTM (DKKm)



Operating costs and operating results

In the first quarter of 2017, production costs totaled DKK 1.6 million, bringing gross profit to DKK 4.2 million and the gross margin to 72%. This is slightly lower than the gross margin of 75% in same period in 2016 and mainly related to an inventory write-down of expired products.

Capacity costs in the first quarter of 2017 amounted to DKK 13.4 million against DKK 9.3 million last year. Capacity costs have increased due to higher activities related to the FDA approval process, establishing a US subsidiary in Q1 2016 and introduction of a warrant program. The restructuring which BioPorto launched in the fall of 2016 is still being implemented and will reduce capacity cost with DKK 3.0 million in 2017 and DKK 4.0 million in 2018, once all initiatives are fully implemented.

In the first quarter of 2017 BioPorto's operating loss before interest and tax (EBIT) amounted to DKK 9.3 million compared to a loss of DKK 5.4 million the previous year.

Profit/loss before and after tax

Net financials in first quarter 2017 were DKK -0.1 million, which is equivalent to the same period in 2016. Pre-tax loss for the first quarter of 2017 is thus DKK 9.4 million compared to a loss of DKK 5.5 million in the first quarter of 2016.

After income recognition of tax of DKK 0,9 million in the period, the net profit for the period amounts to a loss of DKK 8.5 million compared to a loss of DKK 5.1 million last year which is on par with expectations.

Balance sheet

At the end of March 2017, BioPorto's balance sheet totaled DKK 45.9 million. Long-term assets were DKK 3.0 million, a modest reduction of DKK 0.1 million compared to December 31, 2016.

Inventories and receivables amounted to DKK 13.7 million by the end of March 2017 compared to DKK 12.4 million at the same time last year. The cash position was DKK 29.2 million as of March 31, 2017.

At the end of March 2017, equity amounted to DKK 36.4 million compared to DKK 44.3 million at the beginning of the year. Liabilities at March 31, 2017 totaled DKK 9.5 million and consisted primarily of trade payables and other debt.

Cash flow statement

Cash flows generated by operating activity were DKK -6.4 million in the first quarter of 2017 compared to DKK -4.8 million last year. Investments in the period amounted to DKK 0.01 million and cash flows generated by financing activities were DKK 0.01 million. The cash flows for the period thus ended up at DKK -6.4 million compared to DKK -5.2 million in the first quarter of 2016.

Significant events after the end of the period

In April 2017, The Board of directors of BioPorto decided to establish a warrant program and to issue a total of 4.350,000 warrants to BioPorto's management and specific employees. The issuance of new warrants will support the company's long-term goals and establish a performance-based remuneration reflecting the company's and shareholders' interests. Vesting is based on the company's ability to successfully receive FDA approval of The NGAL Test™ before 31st December 2018. The accounting impact of the grant of warrants and the share-based incentive payment is expected to amount to DKK -1.0 million at EBIT level in 2017, which is included in the guidance for the financial year.

Accounting policies

The interim report is presented in accordance with the accounting policies applied in the Group's annual report for 2016.

Focus on FDA process and sales of The NGAL Test™

The managements priorities for the remaining part of 2017 comprise:

- Clinical site planning, patient recruitment and study overview for clinical studies relating to FDA registration of NGAL
- Increase the number of Research Use Only sites for The NGAL Test™ in the US
- Increase non-US sales of The NGAL Test™
- Launch of new immunodeficiency products

Guidance for 2017 maintained

In 2017, BioPorto expects to generate revenue of around DKK 25–28 million, equivalent to a growth rate of 20–35%. The growth will primarily be generated as higher revenue from The NGAL Test™, but revenue generated by the antibody portfolio and ELISA kits also needs to be increased through targeted sales efforts.

Costs for new clinical studies and other procedures relating the application for registration of The NGAL Test™ in the US are expected to amount to around DKK 10 million in 2017. On the other hand, the initiatives BioPorto implemented in the last half of 2016 to reduce overhead are expected to reduce costs by DKK 3 million in 2017. EBIT forecast for the financial year 2017 is a loss between DKK 26-29 million, including non-liquidity constraining cost for a recently established warrant program.

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, 2017 – March 31, 2017.

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, 2017 – March 31, 2017.

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, 2017

Management board:

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Peter Mørch Eriksen
CEO

Board of Directors:

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Thomas Magnussen
Chairman

_____
Torben A. Nielsen
Vice chairman

_____
Kirsten Drejer

_____
Niels Christian Nielsen

Statement of comprehensive income (condensed)

Income statement

Note		2017 3 months DKK thousand	2016 3 months DKK thousand	2016 12 months DKK thousand
1	Revenue	5,743	5,183	20,720
	Gross profit/loss	**4,156**	3,884	15,693
	Profit/loss before financial items (EBIT)	**(9,287)**	**(5,447)**	**(25,047)**
	Profit/loss before tax	**(9,424)**	**(5,540)**	**(24,899)**
	Profit/loss for the period	**(8,549)**	**(5,086)**	**(22,800)**
		DKK	DKK	DKK
	Profit/loss / comprehensive income per share (EPS & DEPS)	(0.06)	(0.04)	(0.17)

Statement of comprehensive income

		2017 3 months DKK thousand	2016 3 months DKK thousand	2016 12 months DKK thousand
	Profit/loss for the period	**(8,549)**	**(5,086)**	**(22,800)**
	Amounts which will be re-classified to the income statement:			
	Exchange rate adjustment foreign subsidiaries	(20)	36	(313)
	Comprehensive income	**(8,569)**	**(5,050)**	**(23,113)**
		DKK	DKK	DKK
	Profit/loss / comprehensive income per share (EPS & DEPS)	(0.06)	(0.04)	(0.18)

Balance sheet

ASSETS	2017 31 March DKK thousand	2016 31 March DKK thousand	2016 31 December DKK thousand
Non-current assets			
Property, plant and equipment and intangible assets			
Fixtures and fittings, tools and equipment	359	563	400
Rights and software	1,885	704	1,959
Total financial assets	710	690	710
Total non-current assets	**2,954**	**1,957**	**3,069**
Current assets			
Total inventories and receivables	13,692	12,433	11,931
Cash	29,214	29,673	35,641
Total current assets	**42,906**	**42,106**	**47,572**
TOTAL ASSETS	**45,860**	**44,063**	**50,641**

Balance sheet

LIABILITIES	2017 31 March DKK thousand	2016 31 March DKK thousand	2016 31 December DKK thousand
Equity			
Share capital	142,494	129,599	142,494
Treasury shares	0	0	0
Exchange-rate adjustments	(333)	36	(313)
Retained earnings	(105,794)	(90,315)	(97,890)
Total equity	**36,367**	**39,320**	**44,291**
Liabilities			
Non-current liabilities			
Lease obligation	34	58	40
Other non-current liabilities	1,164	0	1,164
Non-current liabilities	**1,198**	**58**	**1,204**
Current liabilities			
Current portion of non-current liabilities	243	22	242
Trade payables	3,982	1,004	1,169
Other payables	4,070	3,659	3,735
Current liabilities	**8,295**	**4,685**	**5,146**
Total liabilities	**9,493**	**4,743**	**6,350**
TOTAL LIABILITIES	**45,860**	**44,063**	**50,641**

Statement of changes in equity

	Share capital DKK thousand	Exchange-rate adjust-ments DKK thousand	Retained earnings DKK thousand	Total DKK thousand
Equity 1 January 2017	142,494	(313)	(97,890)	**44,291**
Profit/loss for the year / Comprehensive income	0	0	(8,549)	**(8,549)**
Other changes in equity	0	(20)	645	**625**
Transferred to Retained earnings	0	0	0	**0**
Equity at 31 March 2017	**142,494**	**(333)**	**(105,794)**	**36,367**

	Share capital DKK thousand	Exchange-rate adjust-ments DKK thousand	Retained earnings DKK thousand	Total DKK thousand
Equity 1 January 2016	129,599	0	(85,114)	**44,485**
Profit/loss for the year/ comprehensive income	0	0	(5,086)	**(5,086)**
Other changes in equity	0	36	(115)	**(79)**
Transferred to Retained earnings	0	0	0	**0**
Equity at 31 March 2016	**129,599**	**36**	**(90,315)**	**39,320**

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Cash flow statement

	2017 3 months DKK thousand	2016 3 months DKK thousand	2016 12 months DKK thousand
Profit/loss before financial items	(9,287)	(5,447)	(25,047)
Amortisation, depreciation and impairment losses	151	90	390
Warrants	645	0	2,061
Cash generated from operations before working capital	**(8,491)**	**(5,357)**	**(22,596)**
Changes in working capital	2,145	710	839
Cash generated from operations	**(6,346)**	**(4,647)**	**(21,757)**
Financials, net	(63)	(55)	(124)
Establishment cost, subsidiaries	0	(115)	(115)
Tax refund	0	0	2,336
Cash flows from operating activities	**(6,410)**	**(4,817)**	**(19,660)**
Purchase of operating equipment	(12)	(157)	(157)
Purchase of rights and software	0	(190)	(200)
Purchase of financial assets	0	(25)	(44)
Sale of operating equipment	0	0	0
Cash flows from investing activities	**(12)**	**(372)**	**(401)**
Capital increases	0	0	20,858
Reduction of lease obligation	(5)	(5)	(22)
Cash flows from financing activities	**(5)**	**(5)**	**20,836**
Net cash flow from operating, investing and financing activities	**(6,427)**	**(5,194)**	**774**
Cash and cash equivalents at beginning of period	35,641	34,867	34,867
Cash and cash equivalents end of period	**29,214**	**29,673**	**35,641**

Segments

GEOGRAPHIC DISTRIBUTION:	2017 3 months DKK thousand	2016 3 months DKK thousand	2016 12 months DKK thousand
Denmark	398	366	1,898
Rest of Europe	2,128	2,331	8,182
North America	2,610	1,993	7,760
Asia	593	339	2,656
Other countries	14	154	224
Revenue	**5,743**	**5,183**	**20,720**

PRODUCT GROUPS	2017 3 months DKK thousand	2016 3 months DKK thousand	2016 12 months DKK thousand
The NGAL test	1,245	876	4,014
ELISA Human NGAL kits	227	500	1,720
ELISA Animal NGAL kits	418	270	1,302
ELISA MBL kits	605	343	2,347
Antibodies*	3,110	2,942	10,192
Other products and licenses	138	252	1,145
Revenue	**5,743**	**5,183**	**20,720**

* In Q1 2017, public innovation assistance of DKK 210 thousand relating to the development and production of a new antibody is included as revenue (Q1 2016: DKK 283 thousand and Q1-Q4 2016: DKK 1.334 DKK thousand).