

Interim Report

First Quarter 2018, BioPorto Group

May 3, 2018

Announcement no. 10

Highlights

Important milestones in global roll-out of The NGAL Test™ secured in first quarter 2018

In the first quarter of 2018, BioPorto secured multiple important milestones in the effort to commence a global roll-out of The NGAL Test™.

Firstly, the last patient was enrolled in the US clinical study for The NGAL Test™, and the analysis and preparations for the FDA application has entered into its final phase. This will lead to the US registration application for The NGAL Test™ being submitted to the FDA in second quarter of 2018 as planned.

Secondly, BioPorto and Roche Diagnostics entered into an agreement for exclusive global distribution of a customized version of The NGAL Test™ on Roche equipment. This agreement, together with the existing distribution agreement with Siemens Healthcare, will have significant importance going forward for the global awareness and availability of NGAL as a diagnostic biomarker for acute kidney injury.

Revenue affected by strong focus on strategic execution in beginning of 2018

The strong focus on the execution of the important strategic FDA clinical milestones in the first quarter of 2018 impacted BioPorto's revenue which was down DKK 1.1 million to DKK 4.6 million, primarily due to sales being pushed from first to the quarters to come, for antibodies and the NGAL Test™.

BioPorto's operating loss before interest and tax (EBIT) for the first three months of 2018 was DKK 12.6 million compared to a loss of DKK 9.3 million last year in the same period. The increase in the loss is primarily related to lower revenue and higher research and development costs associated with the US clinical study.

Sales and EBIT guidance for 2018 maintained

After first quarter 2018 management reiterates its guidance for revenue in 2018 of approximately DKK 35 million, corresponding to a minimum growth of 35% over 2017, and an EBIT loss of DKK 32 - 37 million for the financial year 2018.

Peter M. Eriksen, CEO comments: "First quarter 2018 was focused on establishing the foundation for BioPorto's future growth with NGAL. A very important global distribution agreement with one of the largest diagnostic companies in the world, Roche Diagnostics, was signed; we finalized the enrollment of patients for the US clinical study of The NGAL Test™ and are now moving into the final phase of preparing our FDA application which will be submitted shortly. In addition, we took steps to strengthen our team with the addition of Britt Meelby Jensen to the Board of directors, and Ole Larsen as our new CFO – which strengthens our leadership and assures stability and strategic focus for years to come. Allocation of most of BioPorto's resources to concluding the FDA trial, establishing a key distribution relationship with Roche and strengthening the BioPorto team did have an adverse effect on our topline this quarter, but we are confident that growth will increase in the quarters to come, as we finalize the FDA application and shift our focus to sales and preparation for the US launch of the approved The NGAL Test™ later this year."

Investor meeting

In connection with the release of the interim report for the first quarter of 2018, BioPorto will host an investor meeting on May 3, 2018 at 3 pm. The meeting will be held at Tuborg Havnevej 15 st., 2900 Hellerup, Denmark. To attend the meeting, please sign up at investor@bioporto.com.

Financial highlights

	2018 3 months DKK thousand	2017 3 months DKK thousand	2017 12 months DKK thousand
Revenue	4,613	5,743	25,155
Operating profit/loss (EBIT)	(12,553)	(9,287)	(36,494)
Net financials	49	(137)	(571)
Operating profit/loss before tax	(12,504)	(9,424)	(37,064)
Profit/loss for the period	(11,221)	(8,549)	(32,243)
Total comprehensive income	(11,253)	(8,569)	(32,000)
Non-current assets	2,749	2,954	2,623
Current assets (excl. Cash)	16,952	13,692	15,901
Cash	33,749	29,214	47,080
Total assets	53,450	45,860	65,604
Share capital	155,510	142,494	155,510
Equity	45,401	36,367	56,068
Non-current liabilities	725	1,198	883
Current liabilities	7,324	8,295	8,653
Total equity and liabilities	53,450	45,860	65,604
Cash flows from operating activities	(12,922)	(6,410)	(29,399)
Cash flows from investing activities, net	(252)	(12)	(59)
Of which investment in property, plant and equipment	(252)	(12)	(38)
Cash flows from financing activities	(157)	(5)	40,897
Total cash flows	(13,331)	(6,427)	11,439
Revenue growth	-20%	11%	21%
Gross margin	70%	72%	73%
EBIT margin	-272%	-162%	-145%
Equity ratio (solvency)	85%	79%	85%
Return on equity	-22%	-21%	-64%
Average number of employees	24	25	25
Average number of shares (1,000)	155,510	142,494	144,562
Earnings per share (EPS), DKK	(0.07)	(0.06)	(0.22)
Net asset value per share, year-end, DKK	0.29	0.26	0.36
Share price, period-end, DKK	3.21	2.39	3.31

Management review

Enrollment of patients for The NGAL Test™ clinical study in the US finalized - Focus now on preparing the registration application to FDA

In the beginning of March 2018, BioPorto reached an important milestone, when the enrollment of patients for the clinical study forming the data for BioPorto's FDA application for The NGAL Test™ in the US was finalized.

The enrollment was extended to secure additional patients with acute kidney injury for the study and to address inclusion of the Roche instruments covered under the distribution agreement, see below.

Having concluded the patient enrollment for the clinical study, resources have now been allocated to analyzing the data and finalizing the application which will be a major stepping stone in realizing the huge market potential for The NGAL Test™ going forward.

The process of finalizing the application is progressing according to schedule and BioPorto expects to submit its registration application for The NGAL Test™ to the FDA in the second quarter of 2018. Assuming a normal and successful review and approval process, US-registration of The NGAL Test™ is likely to be obtained in the second half of 2018.

BioPorto enters into a new important global distribution agreement with Roche Diagnostics for NGAL

In February 2018, BioPorto entered into an important global distribution agreement with Roche Diagnostics under which Roche Diagnostics will have worldwide exclusive distribution rights for a customized version of The NGAL Test™ for use on Roche's Cobas c501/c502 systems.

The agreement will be of great strategic importance for BioPorto to increase the global availability of NGAL tests and expand the awareness of NGAL as a diagnostic marker for acute kidney injury. The agreement is expected to generate revenue from 2019 once the test has been adapted to the Roche equipment.

Revenue from The NGAL Test™ in US continues to grow, but overall sales down as focus is on submitting FDA application

Sales of The NGAL Test™ for Research Use Only (RUO) continues to grow in the US. In the first quarter of 2018, RUO sales grew 26% supported by an increasing interest in the test from clinics, hospitals and patient organizations such as the National Kidney Foundation.

Sales of The NGAL Test™ in the rest of the world were negatively affected by the allocation of resources within the organization to focus on the US clinical study and preparation of the FDA application for the test. Also, allocation of tests for the clinical study resulted in a back log, which BioPorto expects to resolve in the second quarter of 2018. This meant that overall sales of The NGAL Test™ fell 30% in the first quarter of 2018 compared to the same quarter last year.

ELISA kits increase, but antibody sales affected by postponement of order

Sales of ELISA kits increased by 11% in the first quarter of 2018 over the same quarter in 2017, while revenue from antibodies was reduced from DKK 3.1 million to DKK 2.1 million as a few large orders were pushed from first quarter to the quarters to come.

Strengthening of the Board of Directors and management team with new appointments

At the Annual General Meeting held on April 13, 2018, Britt Meelby Jensen, was elected to the Board of Directors for BioPorto A/S. Mrs. Jensen, M.Sc. and MBA, has extensive global commercial and general management experience from working in the life sciences area over the past 16 years at Novo Nordisk, Dako and from 2015 as CEO of Zealand Pharma A/S, the Danish biotech company listed on NASDAQ in Copenhagen and New York.

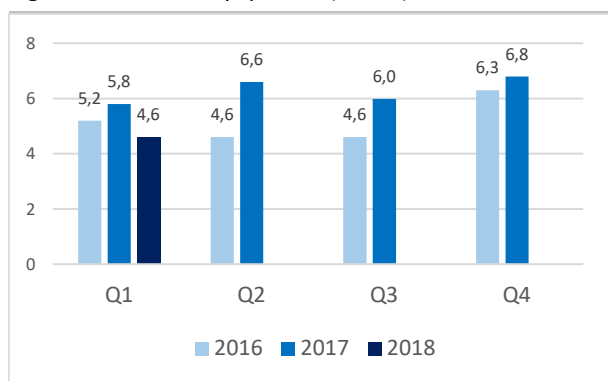
Furthermore, BioPorto in April 2018 announced the appointment of Ole Larsen, M.Sc., as CFO of the company from June 2018. Mr. Larsen, previously was CFO at the Danish listed biotech company Bavarian Nordic, and brings comprehensive international experience and knowledge of the industry. Ole will be joining the management team consisting of Peter Mørch Eriksen (CEO) and Jan Kuhlmann Andersen (COO).

Financial review

Revenue

BioPorto's revenue in first quarter 2018 was DKK 4.6 million against DKK 5.7 million in first quarter 2017. This result was primarily attributable to a decrease in the sales of antibodies and focus on submitting the FDA application for The NGAL Test™.

Figure 1. Revenue by quarter (DKKm)



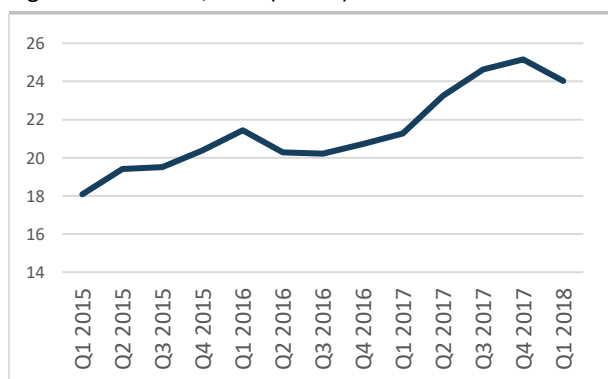
Sales of The NGAL Test™ (RUO) in the US grew by 26% in first quarter 2018 as a result of the targeted focus on expanding the knowledge of NGAL. Growth was lower than previous quarters as most of BioPorto's resources in the quarter had been allocated to collecting and preparing the FDA application planned for submission in second quarter of 2018.

This also affected revenue in rest of the world for The NGAL Test™, which was down 51%. Also, The NGAL Test™ kits were prioritized to support the FDA clinical study, thereby resulting in a back log of orders which will be fulfilled in the coming quarters.

Sales of antibodies declined from DKK 3.1 million last year in first quarter to DKK 2.1 million in first quarter 2018. The development was caused by a few larger orders being pushed from the first quarter to the quarters to come.

Altogether, revenue from ELISA kits increased 11% in the first quarter of 2018, driven by higher sales of ELISA Human NGAL kits and ELISA MBL kits.

Figure 2. Revenue, LTM (DKKm)



Operating costs and operating results

For the first 3 months of 2018, production costs totaled DKK 1.4 million, bringing the gross profit to DKK 3.2 million and the gross margin to 70%. The gross margin was 72% in same period in 2017 and the decrease is mainly related to exchange rates and product-mix.

Capacity costs year-to-date amounted to DKK 15.8 million versus DKK 13.4 million last year. Capacity costs have increased predominantly due to higher research and development costs associated with the US clinical study. The aim of the clinical study is to get an FDA approval for BioPorto's The NGAL Test™ which will allow BioPorto to commercialize the product in the US for diagnostic use.

In the first three months of 2018 BioPorto's operating loss before interest and tax (EBIT) amounted to DKK 12.6 million compared to a loss of DKK 9.3 million in the previous year. The increased loss is a result of the lower revenue and higher cost for the US clinical study.

Profit/loss before and after tax

Net financials for the first 3 months in 2018 were DKK 0.1 million, which is on par with 2017. After income recognition of tax of DKK 1,3 million in this period, the net profit for the period amounts to a loss of DKK 11.2 million compared to a loss of DKK 8.5 million for the first three month of 2017.

Balance sheet

At the end of March 2018, BioPorto's balance sheet totaled DKK 53.5 million. Total non-current assets were DKK 2.7 million, a modest increase of DKK 0.1 million compared to December 31, 2017.

Inventories and receivables amounted to DKK 9.2 million by the end of March 2017, compared to DKK 9.3 million on March 31, 2017. The cash position was DKK 33.7 million as of March 31, 2018.

At the end of March 2018, equity amounted to DKK 45.4 million compared to DKK 56.1 million at the beginning of the year. Liabilities on March 31, 2018 totaled DKK 8.0 million and consisted primarily of trade payables and other debt.

Cash flow statement

Cash flows generated by operating activity were DKK -12.9 million in the first 3 months of 2018 compared to DKK -6.4 million last year. Investments in the period amounted to DKK 0.1 million and cash flows generated by financing activities were DKK -0.2 million. The cash flows for the period thus ended up at DKK -13.3 million compared to DKK -6.4 million in the first 3 months of 2017.

Accounting policies

The interim report for the first three months of 2018 has been prepared in accordance with IAS 34 and the additional Danish regulations for the presentation of quarterly interim reports by listed companies. The interim report is presented as condensed interim financial statements.

The interim report for the first three months of 2018 follows the same accounting policies as the annual report for 2017, except for new accounting standards and interpretations (IFRSs) endorsed by the EU effective for the

accounting period beginning on January 1, 2018. This includes IFRS 9 'Financial Instruments: Classification and Measurement of Financial Assets and Financial Liabilities' and IFRS 15 'Revenue from Contracts with Customers'.

The implementation of IFRS 9 and IFRS 15 has not had an impact on the income statement or the balance sheet at 1 January 2018 or at Q1 2018. Neither has affected the related key ratios in the consolidated financial statements.

Both IFRS 9 and IFRS 15 have been implemented modified retrospective and the implementation of both standards have not affected comparatives.

Updated accounting policy for revenue

Revenue from the sale of finished goods is recognized in the income statement when the performance obligations have been satisfied. This happens when the products have been transferred to the customer and the customer obtains control of the products, and if the income can be reliably measured and is expected to be received. Revenue from the sale of products is recognized at a point in time, when control transfers to the customer.

Revenue from development and collaboration contracts is recognized in the income statement using the five-step model in IFRS 15:

This is considered to be the case when:

- » Binding contract with a customer has been entered into;
- » The performance obligations have been identified;
- » The selling price has been determined;
- » The selling price has been allocated to performance obligations;
- » The performance obligations have been fulfilled

Revenue is recognized excluding VAT and net of discounts related to sales.

Updated accounting policy for Receivables

Receivables are measured to the nominal value less provisions for expected loss.

Expected loss on receivables is based on an individual assessment of receivables.

Focus on concluding the clinical study recruitment and increasing sales of The NGAL Test™

Managements priorities for 2018 are:

- » Finalizing and submitting the FDA application for registration of The NGAL Test™
- » Ramping up marketing activities for The NGAL Test™ and adding resources to the US organization
- » Strengthening sales activities to increase sales of the antibody portfolio and in particular The NGAL Test™, both in current markets and in RUO sales in USA.
- » Evaluate other indications for NGAL and initiate market review to assess optimal strategy and capitalization of BioPorto going forward

Guidance for 2018 maintained

Based on the results of the first quarter 2018, BioPorto maintains its guidance for the financial year 2018. Revenue in 2018 is expected to total approximately DKK 35 million, corresponding to a minimum growth of 35% over 2017. Growth will primarily be driven by an increase in revenue from The NGAL Test™ for RUO in the USA and to a lesser degree by partner sales from recent distributor deals in rest of the world and increases in sales from antibodies.

EBIT for the financial year 2018 is forecasted to be a loss of DKK 32 - 37 million impacted by the cost associated with the finalization of the FDA application and increased marketing activities to build awareness of the test.

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, 2018 – March 31, 2018.

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 as of March 31, 2018, and of the results of the Group's operations and cash flows for the period January 1, 2018 – March 31, 2018.

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 3, 2018

Management board:

Peter Mørch Eriksen
CEO

Board of Directors:

Thomas Magnussen
Chairman

Torben A. Nielsen
Vice chairman

Kirsten Drejer

Britt Meelby Jensen

Statement of comprehensive income

Income statement

	2018	2017	2017
	3 months DKK thousand	3 months DKK thousand	12 months DKK thousand
Revenue (note 1)	4,613	5,743	25,155
Production costs	(1,404)	(1,586)	(6,907)
Gross profit/loss	3,209	4,156	18,248
Sales and marketing costs	(5,017)	(4,982)	(18,545)
Research and development costs	(5,965)	(4,138)	(21,930)
Administrative expenses	(4,780)	(4,323)	(14,267)
Profit/loss before financial items (EBIT)	(12,553)	(9,287)	(36,494)
Financials net	49	(138)	(570)
Profit/loss before tax	(12,504)	(9,424)	(37,064)
Total income taxes	1,282	876	4,821
Profit/loss for the period	(11,221)	(8,549)	(32,243)
	DKK	DKK	DKK
Profit/loss / comprehensive income per share (EPS & DEPS)	(0.07)	(0.06)	(0.22)

Statement of comprehensive income

	2018	2017	2017
	3 months DKK thousand	3 months DKK thousand	12 months DKK thousand
Profit/loss for the period	(11,221)	(8,549)	(32,243)
Amounts which will be re-classified to the income statement:			
Exchange rate adjustment foreign subsidiaries	(32)	(20)	243
Comprehensive income	(11,253)	(8,569)	(32,000)

Balance sheet

ASSETS	2018 31 March DKK thousand	2017 31 March DKK thousand	2017 31 December DKK thousand
Non-current assets			
Property, plant and equipment and intangible assets			
Fixtures and fittings, tools and equipment	466	359	263
Rights and software	1,552	1,885	1,629
Total property, plant and equipment and intangible assets	2,018	2,244	1,892
Financial assets			
Deposits	731	710	731
Total financial assets	731	710	731
Total non-current assets	2,749	2,954	2,623
Current assets			
Inventories	3,139	4,369	3,434
Trade receivables	6,072	4,899	6,380
Income tax receivable	6,136	3,048	4,864
Other receivables	1,605	1,376	1,223
Total inventories and receivables	16,952	13,692	15,901
Cash	33,749	29,214	47,080
Total current assets	50,701	42,906	62,981
TOTAL ASSETS	53,450	45,860	65,604

Balance sheet

LIABILITIES	2018 31 March DKK thousand	2017 31 March DKK thousand	2017 31 December DKK thousand
Equity			
Share capital	155,510	142,494	155,510
Treasury shares	0	0	0
Exchange-rate adjustments	(102)	(333)	(70)
Retained earnings	(110,007)	(105,794)	(99,372)
Total equity	45,401	36,367	56,068
Liabilities			
Non-current liabilities			
Lease obligation	0	34	0
Other non-current liabilities	725	1,164	883
Non-current liabilities	725	1,198	883
Current liabilities			
Current portion of non-current liabilities	163	243	182
Trade payables	2,933	3,982	3,412
Other payables	4,228	4,070	5,059
Current liabilities	7,324	8,295	8,653
Total liabilities	8,049	9,493	9,536
TOTAL LIABILITIES	53,450	45,860	65,604

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 2018	155,510	(70)	(99,372)	56,068
Comprehensive income				
Profit/loss for the year / Comprehensive income	0	0	(11,221)	(11,221)
Other changes in equity	0	(32)	586	554
Equity at 31 March 2018	155,510	(102)	(110,007)	45,401

	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
Comprehensive income				
Profit/loss for the year/ comprehensive income	0	0	(8,549)	(8,549)
Other changes in equity	0	(20)	645	625
Equity at 31 March 2017	142,494	(333)	(105,794)	36,367

Cash flow statement

	2018 3 months DKK thousand	2017 3 months DKK thousand	2017 12 months DKK thousand
Profit/loss before financial items	(12,553)	(9,287)	(36,494)
Amortization, depreciation and impairment losses	126	151	504
Warrants	586	645	2,856
Cash generated from operations before working capital	(11,841)	(8,491)	(33,134)
Changes in working capital	(1,089)	2,145	2,325
Cash generated from operations	(12,930)	(6,346)	(30,809)
Financials, net	8	(63)	(595)
Tax refund	0	0	2,005
Cash flows from operating activities	(12,922)	(6,410)	(29,399)
Purchase of operating equipment	(252)	(12)	(38)
Purchase of financial assets	0	0	(21)
Cash flows from investing activities	(252)	(12)	(59)
Capital increases	0	0	40,921
Reduction of non-current liabilities	(157)	(5)	(24)
Cash flows from financing activities	(157)	(5)	40,897
Net cash flow from operating, investing and financing activities	(13,331)	(6,427)	11,439
Cash and cash equivalents at beginning of period	47,080	35,641	35,641
Cash and cash equivalents end of period	33,749	29,214	47,080

Segments

GEOGRAPHIC DISTRIBUTION:

	2018 3 months DKK thousand	2017 3 months DKK thousand	2017 12 months DKK thousand
Denmark	58	398	1,481
Rest of Europe	2,180	2,128	8,818
North America	1,807	2,610	10,900
Asia	423	593	3,676
Other countries	145	14	280
Revenue	4,613	5,743	25,155

PRODUCT GROUPS

	2018 3 months DKK thousand	2017 3 months DKK thousand	2017 12 months DKK thousand
The NGAL test	877	1,245	6,426
ELISA Human NGAL kits	388	227	1,448
ELISA Animal NGAL kits	336	417	1,672
ELISA MBL kits	668	605	2,608
Antibodies*	2,147	3,110	12,199
Royalty	39	3	89
Other products and licenses	158	136	713
Revenue	4,613	5,743	25,155

* In Q1 2018, public innovation assistance of DKK 0 thousand relating to the development and production of a new antibody is included as revenue (Q1 2017: DKK 210 thousand and Q1-Q4 2017: DKK 843 DKK thousand).

