

5 May 2015

Announcement no. 11

## Interim financial report for Q1 2015 – the BioPorto Group

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### Summary

#### Convincing progress in NGAL activities

- In the first quarter of 2015, we added six new routine users of The NGAL Test™, bringing the total number of clinics and centres regularly using the test to 19 at the end of March 2015. Sales of The NGAL Test™ increased by 68% compared with Q1 2014.
- BioPorto has completed an accelerated enrolment of patients for the clinical trial with The NGAL Test™ in the USA and expects to submit a 510(k) application to the FDA in the summer of 2015.
- We increased the portfolio of ELISA kits and antibodies by 25 new antibodies Q1, consolidating the basis for generating higher add-on sales.

#### Financial performance in line with expectations

- BioPorto generated revenue of DKK 4.1 million in Q1 2015, against DKK 4.8 million in the year-earlier period, when revenue was positively affected by license income from Abbott. Net of this income, revenue was up by approximately 14% compared with Q1 2014.
- First-quarter research and development costs rose by about DKK 900,000 relative to last year because of the accelerated clinical trials in the USA. Other capacity costs were reduced by 10% owing to improved efficiency.
- EBIT was a loss of DKK 4.4 million (2014: loss of DKK 3.6 million), and the loss for the period was DKK 4.0 million (2014: loss of DKK 3.6 million).

#### Guidance for 2015 maintained

- Revenue is expected to be DKK 22-25 million in 2015, representing an increase of approximately 15-35% on 2014.
- EBIT for 2015 is forecast at a loss between DKK 10 and 12 million, and we expect a net loss at the level of DKK 8 to 10 million.

Peter Mørch Eriksen, CEO, said: *"The substantial strategic initiatives we made with The NGAL Test™ in 2014 are beginning to produce results. There is growth in the number of routine users routine usage, and the test is generating growing revenue in Europe. Within a very short period of time, we have completed an accelerated patient enrolment in the USA, where we are currently preparing the 510k application for the test to be submitted to the FDA. We will now start to set up our business foundation in the USA and prepare to launch the test after our registration application for the test has been approved, expectedly at the end of 2015. In terms of efficiency, disregarding the increased cost of completing clinical trials, we have reduced our capacity costs by 10%, so we are in every way on track to meet our targets."*

#### Investor meeting

In connection with the release of the Q1 2015 interim report, BioPorto will arrange an investor meeting to be held on Tuesday 5 May 2015 at 3:00 pm at the company's address, Tuborg Havnevej 15, DK-2900 Hellerup, Denmark.

## Financial highlights

	2015 3 months DKK thousands	2014 3 months DKK thousands	2014 12 months DKK thousands
Net revenues .....	4.129	4.751	18.705
Net income/loss, ordinary operating act (EBIT) .....	(4.427)	(3.624)	(15.256)
Income/loss from net financials .....	(60)	12	159
Earnings before tax .....	(4.487)	(3.612)	(15.097)
Net income/loss for the period .....	(3.977)	(3.612)	(12.926)
Long-term assets .....	1.419	1.751	1.456
Short-term assets .....	31.394	44.506	35.783
Total assets .....	32.813	46.257	37.239
Capital stock .....	117.874	117.861	117.874
Equity .....	24.709	38.000	28.686
Long-term liabilities .....	80	101	87
Short-term liabilities .....	8.024	8.156	8.466
Total liabilities .....	32.813	46.257	37.239
Cash flow from by operations .....	(3.410)	(5.414)	(16.138)
Cash flow from investing, net .....	(33)	(1.273)	(1.199)
Of which invested in property, plant and equipment .....	0	(361)	(542)
Cash flow from financing .....	(5)	(4)	(18)
Total cash flow .....	(3.448)	(6.691)	(17.355)
Revenue growth .....	-13%	58%	13%
Gross margin ratio .....	65%	67%	71%
Operating margin .....	-107%	-76%	-82%
Equity interest (equity ratio) .....	75%	82%	77%
Return on equity .....	-15%	-9%	-37%
Average no. of employees .....	26	25	24
Average no. of shares (1,000) .....	117.874	117.874	117.874
Earnings per share (EPS) DKK .....	(0,03)	(0,03)	(0,11)
Equity value per share, closing, DKK .....	0,21	0,32	0,24
Listed price, closing, DKK .....	1,67	3,55	1,69

**Sharp increase in number of routine users of The NGAL Test™**

Our strategy for The NGAL Test™ in Europe targets the areas of heart surgery and kidney transplantation, for which we seek to increase the number of centres that are routine users of the test through a dedicated sales effort. Since the beginning of 2015, we have increased the number of routine users in Europe by another four centres. In the USA, two centres have started to regularly use the test for research purposes, bringing the total number of clinics and centres that are routine users to 19 at the end of March 2015.

Because of limited awareness of NGAL, decision-making processes at European clinics and centres remain cumbersome. However, our targeted sales strategy and mounting academic acceptance and awareness of NGAL as a superior biomarker of acute kidney injury have helped lift sales.

As a result of the increase in the number of routine users, revenue from The NGAL Test™ rose by 68% in Q1 2015 compared with the year-earlier period. Although the increase is from a moderate level, the positive trend bears witness to mounting interest in The NGAL Test™ for diagnosing acute kidney injury.

**Partnering efforts facilitated by increase in routine users**

BioPorto has defined a target of a minimum of 25 routine users in Europe by the end of 2015. Achieving this target should contribute to increasing the number of agreements with distributors and potential licensing and OEM partners, leading to more widespread use of The NGAL Test™. We maintain our intensive focus on sales through partnerships and expect to announce additional licensing and OEM agreements not later than in [Q3] 2015.

**Accelerated patient enrolment for clinical trials in the USA with The NGAL Test™ completed**

In March, BioPorto completed its accelerated enrolment of patients for the clinical trial that forms part of the 510(k) application for The NGAL Test™ in the USA.

The core data includes sample collections from 250 patients at three sites, which is currently being analysed ahead of 510(k) submission to the FDA. The 510(k) application will be submitted in the summer of 2015 and is expected to lead to approval of The NGAL Test™ in the USA by the end of the year. We have started to build a US business foundation, including the preparation of a sales and distribution strategy for the US market, and we regularly receive enquiries from US clinics concerning our test, which we expect to bring to market in the USA at the beginning of 2016.

**Antibody portfolio strengthened with the aim of lifting sales**

In Q1 2015, BioPorto generated higher revenue from ELISA kits and antibodies than in the same period of last year. The improvement was driven by an increase in revenue of NGAL-based kits, while revenue of MBL kits declined. First-quarter revenue from antibodies were on a level with last year, primarily because of the accrual of a major annual order, which in 2015 is expected to be recognised in Q2 instead of in the first quarter as was the case last year.

In line with its strategy for the area, BioPorto in-licensed 25 new antibodies in the first quarter of 2015, which will be included in the portfolio from April 2015. Together with the expansion opportunities in the assay segment, this should contribute to creating sales synergies and generate higher add-on sales.

**Financial review***Revenue*

BioPorto generated first-quarter revenue of DKK 4.2 million in 2015, down from DKK 4.8 million in the year-earlier period, when license income from Abbott relating to NGAL cross-licensing had a positive impact on revenue. Net of this income, revenue in Q1 2015 was up by approximately 14%, because of stronger sales of NGAL products.

First-quarter sales of The NGAL Test<sup>™</sup> rose by 68% to DKK 752,000 because of the increase in the number of routine users from eight last year to 19 this year. Revenue from kits and antibodies were more or less unchanged at DKK 3.1 million.

#### *Operating costs and operating results*

Production costs amounted to DKK 1.4 million in Q1 2015, which translates into a gross profit of DKK 2.7 million and a gross margin of 65.3% (2014: DKK 3.2 million and 67.1%).

Capacity costs amounted to DKK 7.1 million in Q1 2015, against DKK 6.8 million in the year-earlier period. Costs of conducting the clinical trials with The NGAL Test<sup>™</sup> in the USA resulted in a DKK 900,000 increase in research and development costs compared with last year. On the other hand, administrative expenses were reduced as a result of greater efficiency and fewer employees.

This brought the operating loss to DKK 4.4 million (2014: loss of DKK 3.6 million), which was in line with expectations.

#### *Profit/loss before and after tax*

Net financials in Q1 2015 were an expense of DKK 50,000, which brings the pre-tax loss for Q1 to DKK 4.5 million (2014: loss of DKK 3.6 million).

Recognition of a tax asset of DKK 0.5 million results in a net loss for the period of DKK 4.0 million (2014: loss of DKK 3.6 million), which is in line with expectations.

#### *Balance sheet*

Total assets amounted to DKK 32.8 million at 31 March 2015 (2014: DKK 38.2 million). Non-current assets were unchanged at DKK 1.4 million, while inventories amounted to DKK 9.4 million (2014: DKK 10.3 million), and cash stood at DKK 22.0 million.

Equity amounted to DKK 24.7 million at 31 March 2015, against DKK 28.7 million at the beginning of the year. Liabilities at 31 March 2015 amounted to DKK 8.1 million, consisting primarily of trade payables etc.

#### **Significant events after the end of the period**

No significant events have occurred after the balance sheet date that are not described in this interim report.

#### **Focus on completing the FDA application and growing sales of The NGAL Test<sup>™</sup>**

The management priorities for the remaining part of 2015 comprise:

- Completing and submitting the 510(k) application for The NGAL Test<sup>™</sup> in the US market, while at the same time determine our US sales- and distribution strategy.
- Continuing negotiations with routine users and licensing and OEM partners with the aim of increasing the use of The NGAL Test<sup>™</sup> in Europe.
- Improving the preconditions for maintaining growth in sales of kits and antibodies.

#### **Guidance for 2015 maintained**

On the basis of positive and planned Q1 2015 performance with an increase in the number of routine users of The NGAL Test<sup>™</sup>, completion of enrolment of patients for an FDA application in the USA and expansion of the portfolio of antibodies, we maintain our guidance for 2015 as described in our annual report for 2014.

Revenue is thus expected to be DKK 22-25 million in 2015, representing an increase of approximately 15-35% on 2014.

Combined with greater efficiency, the increase in revenue is expected to lead to an operating loss of DKK 10-12 million, while the loss for the full year is expected to be DKK 8-10 million, which would be a notable improvement on 2014.

**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. We sell our products in more than 80 countries through diverse sales channels. BioPorto is headquartered in Copenhagen, Denmark and is listed on the NASDAQ OMX 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 1 January 2015 – 31 March 2015.

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 31 March 2015 and of the results of the Group's operations and cash flows for the period 1 January 2015 – 31 March 2015.

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, 5 May 2015

**Management Board:**

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Peter Mørch Eriksen  
CEO

**Board of Directors:**

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Thomas Magnussen  
Chairman

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Torben A. Nielsen  
Vice Chairman

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Roar Bjørk Seeger

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Jan Kuhlmann Andersen

**Condensed statement of comprehensive income**  
**BioPorto Group**

## Statement of comprehensive income

	2015 3 months DKK thousands	2014 3 months DKK thousands
Net Revenues.....	4.129	4.751
<b>Gross margin.....</b>	<b>2.695</b>	<b>3.186</b>
<b>Earnings before interest and taxes.....</b>	<b>(4.427)</b>	<b>(3.624)</b>
<b>Earnings before taxes.....</b>	<b>(4.487)</b>	<b>(3.612)</b>
<b>Net profit/Comprehensive income, total.....</b>	<b>(3.977)</b>	<b>(3.612)</b>
	DKK	DKK
Earnings per share (eps/dps)	(0,03)	(0,03)

Condensed balance sheet  
BioPorto Group

## Balance sheet

ASSETS	2015 3 months DKK thousands	2014 12 months DKK thousands	2014 3 months DKK thousands
<b>Long-term assets</b>			
Intangible assets.....	176	199	265
Tangible assets.....	596	612	586
Financial assets.....	647	645	900
<b>Long-term assets, total.....</b>	<b>1.419</b>	<b>1.456</b>	<b>1.751</b>
<b>Short-term assets</b>			
Receivables and inventories.....	9.395	10.336	8.394
Cash resources.....	21.999	25.447	36.112
<b>Short-term assets, total.....</b>	<b>31.394</b>	<b>35.783</b>	<b>44.506</b>
<b>ASSETS, TOTAL.....</b>	<b>32.813</b>	<b>37.239</b>	<b>46.257</b>



Condensed balance sheet  
BioPorto Group

## Balance sheet

<b>LIABILITIES</b>	2015 3 months DKK thousands	2014 12 months DKK thousands	2014 3 months DKK thousands
<b>Equity</b>			
Capital stock.....	117.874	117.874	117.874
Other reserves.....	0	0	0
Reserve, share-based payment.....	648	648	1.666
Treasury stock.....	0	0	0
Retained income/loss.....	(93.813)	(89.836)	(81.540)
<b>Equity, total.....</b>	<b>24.709</b>	<b>28.686</b>	<b>38.000</b>
<b>Liabilities</b>			
<b>Long-term liabilities</b>			
Leasing.....	80	87	101
<b>Long-term liabilities, total.....</b>	<b>80</b>	<b>87</b>	<b>101</b>
<b>Short-term liabilities</b>			
Short-term segment of long-term liabilities.....	20	18	18
Suppliers of goods and services.....	455	1.199	1.462
Other debt.....	7.549	7.249	6.676
<b>Short-term liabilities, total.....</b>	<b>8.024</b>	<b>8.466</b>	<b>8.156</b>
<b>Liabilities, total.....</b>	<b>8.104</b>	<b>8.553</b>	<b>8.257</b>
<b>EQUITY AND LIABILITIES, TOTAL.....</b>	<b>32.813</b>	<b>37.239</b>	<b>46.257</b>

**Statement of changes in equity  
BioPorto Group**
**Equity**

	Capital stock	Treasury stock	Share-based payment	Other reserves	Retained income/loss	Total
	DKK thousands	DKK thousands	DKK thousands	DKK thousands	DKK thousands	DKK thousands
Equity, January 1, 2015.....	117.874	0	648	0	(89.836)	<b>28.686</b>
Comprehensive income for the period.....	0	0	0	0	(3.977)	<b>(3.977)</b>
<b>Equity, March 31, 2015.....</b>	<b>117.874</b>	<b>0</b>	<b>648</b>	<b>0</b>	<b>(93.813)</b>	<b>24.709</b>

	Capital stock	Treasury stock	Share-based payment	Other reserves	Retained income/loss	Total
	DKK thousands	DKK thousands	DKK thousands	DKK thousands	DKK thousands	DKK thousands
Equity, January 1, 2014.....	117.874	0	1.666	0	(77.928)	<b>41.612</b>
Comprehensive income for the period.....	0	0	0	0	(3.612)	<b>(3.612)</b>
<b>Equity, March 31, 2014.....</b>	<b>117.874</b>	<b>0</b>	<b>1.666</b>	<b>0</b>	<b>(81.540)</b>	<b>38.000</b>

**Cash flow statement**  
**BioPorto Group**

## Cash Flow

	2015 3 months DKK thousands	2014 3 months DKK thousands
Earnings before interest (EBIT).....	(4.427)	(3.624)
Depreciation, amortization and write-downs.....	70	50
<b>Cash flow before change in working capital.....</b>	<b>(4.357)</b>	<b>(3.574)</b>
Change in working capital.....	1.008	(1.852)
<b>Cash flow from primary operations.....</b>	<b>(3.349)</b>	<b>(5.426)</b>
Interest income, included.....	47	30
Interest expenses, paid.....	(108)	(18)
<b>Cash flow from operating activities.....</b>	<b>(3.410)</b>	<b>(5.414)</b>
Purchase of intangible assets.....	0	(265)
Purchase of tangible assets.....	(33)	(361)
Purchase of financial assets.....	0	(647)
<b>Cash flow from investing activities.....</b>	<b>(33)</b>	<b>(1.273)</b>
Reduction of lease obligation.....	(5)	(4)
<b>Cash flow from financial activities.....</b>	<b>(5)</b>	<b>(4)</b>
<b>Cash flow for the period.....</b>	<b>(3.448)</b>	<b>(6.691)</b>
Cash balance at the beginning of the year.....	25.447	42.802
<b>Cash balance at the end of the period.....</b>	<b>21.999</b>	<b>36.111</b>

**Accounting policies**

The interim report is presented in accordance with IAS 34 and additional Danish disclosure requirements for interim reports of listed companies. The accounting policies applied in the interim report are unchanged relative to the accounting policies applied in the Group's annual report for 2014.

The consolidated financial statements and the parent company financial statements for 2014 contain the full description of the accounting policies.

**Note 1**

# Note 1

The geographical dispersion of the net revenues is:	2015	2014
	3 months DKK thousands	3 months DKK thousands
Denmark.....	225	159
Other European countries.....	1.904	1.098
North America.....	1.532	2.833
Asia.....	411	380
Other countries.....	57	280
<b>Net revenues, total.....</b>	<b>4.129</b>	<b>4.751</b>

Product groups	2015	2014
	3 months DKK thousands	3 months DKK thousands
The NGAL test.....	752	448
ELISA Human NGAL kits.....	442	229
ELISA Animal NGAL kits.....	282	264
ELISA MBL kits.....	464	521
Antibodies.....	1.948	1.953
Other products and licenses.....	241	1.336
<b>Net revenues, total.....</b>	<b>4.129</b>	<b>4.751</b>

BioPorto's management introduced a new internal reporting procedure in 2014. Sales figures are distributed based on an adjusted distribution of product groups reflecting the focus areas of the new strategy. The previous segments will no longer be used. The sales figures for 2013 have been restated to reflect the new distribution.