

**7 August 2015**  
**Announcement no. 14**

## **Interim financial report for Q2 2015 – the BioPorto Group**

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### **Summary**

#### **New products and progress in FDA application process**

- The collection of data from the clinical study of The NGAL Test™ in the USA is completed. BioPorto assesses that the data support the further application process, including the formulation of the final application, which is expectedly submitted to the FDA in September 2015.
- ELISA kits and antibodies have shown a satisfactory revenue growth in the first half of 2015 at around 10%. The antibody portfolio is extended with a generic strip test under the name gRAD (Generic Rapid Assay Device).
- The revenue growth of The NGAL Test™ in the first half of 2015 was 3%, which is less than expected. The number of routine users is still 19.

#### **Earnings impacted by research and development costs**

- BioPorto generated revenue of DKK 9.9 million in the first half of 2015 against DKK 9.2 million last year, representing a growth of 8%. Revenue for Q2 amounted to DKK 5.8 million. (2014: DKK 4.5 million.), representing a growth of 29%.
- Research and development costs in the first half of 2015 increased by approximately DKK 1.6 million. compared to last year, as a result of the completed clinical trials in the USA. General expenses were reduced as a result of efficiency improvements.
- In the first half of 2015, resources have been used for the commercial preparation for the US market.
- EBIT amounted to DKK -8.5 million (2014: DKK -9.3 million.) and net profit of DKK -7.2 million (2014: DKK -8.2 million.).

#### **Guidance for 2015 revised**

- Revenue is expected to be DKK 22-23 million in 2015, representing a growth of approximately 18% compared to 2014, against the previous guidance of DKK 22-25 million.
- In 2015, an EBIT of DKK 12 million and a net result of DKK -10 million is expected, against previous guidance for EBIT level DKK -10 to -12 million and net profit of DKK -8 to -10 million.

Peter Mørch Eriksen, CEO, comments: *"We are making progress in the FDA process and are getting ready for submission of the application in September. Also, we have begun the commercial preparations for the launch of The NGAL Test™ in the US, and are in the process of defining our sales and distribution strategy. Sales represent the best first half year for BioPorto and are generally satisfactory, although NGAL Q2 sales are slightly behind. Sales are expected to pick up in the second half of 2015 based partly on the addition of new routine users, bringing us up to the aim of 25 routine users, and partly from new products in the AntibodyShop portfolio. We revise our expectations for the full year, and remain on track with respect to the announced strategy."*

### Investor meeting

In connection with the release of the Q2 2015 interim report, BioPorto will arrange an investor meeting to be held on Friday 7 August 2015 at 3:00 pm at the company's address, Tuborg Havnevej 15, DK-2900 Hellerup, Denmark.

### Financial highlights

	2015 2nd quarter DKK thousands	2014 2nd quarter DKK thousands	2015 6 months DKK thousands	2014 6 months DKK thousands	2014 12 months DKK thousands
Net revenues .....	5,804	4,485	9,933	9,236	18,705
Net income/loss, ordinary operating act (EBIT) .....	(4,038)	(5,682)	(8,465)	(9,306)	(15,256)
Income/loss from net financials .....	2	(17)	(58)	(4)	159
Earnings before tax .....	(4,036)	(5,698)	(8,523)	(9,310)	(15,097)
Net income/loss for the period .....	(3,271)	(4,645)	(7,168)	(8,257)	(12,926)
Long-term assets .....	1,546	1,606	1,546	1,606	1,456
Short-term assets .....	27,887	41,311	27,887	41,311	35,783
Total assets .....	29,433	42,916	29,433	42,916	37,239
Capital stock .....	117,874	117,874	117,874	117,874	117,874
Equity .....	20,163	33,355	20,163	33,355	28,686
Long-term liabilities .....	75	96	75	96	87
Short-term liabilities .....	9,195	9,464	9,195	9,464	8,466
Total liabilities .....	29,433	42,916	29,433	42,916	37,239
Cash flow from by operations .....	(3,825)	(4,019)	(7,234)	(9,433)	(16,138)
Cash flow from investing, net .....	(197)	73	(230)	(1,200)	(1,199)
Of which invested in property, plant and equipment ...	(180)	(181)	(50)	(542)	(542)
Cash flow from financing .....	(5)	(4)	(9)	(8)	(18)
Total cash flow .....	(4,026)	(3,951)	(7,473)	(10,641)	(17,355)
Revenue growth .....	29%	5%	8%	27%	13%
Gross margin ratio .....	78%	69%	73%	68%	71%
Operating margin .....	-70%	-127%	-85%	-101%	-82%
Equity interest (equity ratio) .....	69%	78%	69%	78%	77%
Return on equity .....	Negative	Negative	Negative	Negative	Negative
Average no. of employees .....	23	24	24	24	24
Average no. of shares (1,000) .....	117,874	117,874	117,874	117,874	117,874
Earnings per share (EPS) DKK .....	(0.03)	(0.04)	(0.06)	(0.07)	(0.11)
Equity value per share, closing, DKK .....	0.17	0.29	0.17	0.29	0.24
Listed price, closing, DKK .....	2.57	2.32	2.57	2.32	1.69

### **Application for The NGAL Test™ expected to be submitted in September 2015**

In Q2, BioPorto has conducted a preliminary internal assessment of the data from the completed clinical trials in the USA. These data form the basis of the registration application to the FDA for approval of The NGAL Test™. The preliminary internal assessment of data support the further application process, including the formulation of the application, which is expected to be submitted to the FDA in September 2015 at the latest. The coordination of external parties have taken a little longer than expected.

As BioPorto is coming closer to regulatory approval in the US market, the business and resources are focused on the preparation for launch in the US. The establishment of a US business base with sales and support functions, including the development of a strategy for market entry, has high priority. As a start, efforts will be aimed at established contacts and building new relationships with named clinics in selected geographies. Market acceptance and uptake of the test is expected to be much faster in the US than in Europe due to other incentive structures in health care, for example, in the discharge of patients. With a foothold in the selected clinics, The NGAL Test™ is expected to rather rapidly disseminate on a larger scale, partly through increased sales efforts, partly as an effect of the cooperation among the clinics.

### **Moderate growth in sales of the NGAL Test™ in the first half of 2015**

The number of routine users of the NGAL Test™ is by the end of June 2015 at 19, and is thus unchanged from the first quarter of 2015. Continued slow decision processes of European transplant centers and clinics and the accrual is the main reason for the lack of additional routine users in Q2. The aim is still to have a minimum of 25 routine users by the end of 2015.

Sales of The NGAL Test™ in Q2 2015 was approximately DKK 200,000 less than the same quarter last year, when revenue, however, was significantly impacted by a major one-off order for a specific research project.

Overall, sales of The NGAL Test™ in the first half of 2015 increased by 3%, which is less than expected. In the second half of 2015, revenue is expected to rise in line with the addition of further routine users to the portfolio. Following the introduction and widespread use of the NGAL Test™ in the US, a larger interest and acceptance of NGAL as a biomarker for AKI in Europe is expected.

### **AntibodyShop increases sales and plan new product launches in the second half of 2015**

Sales of ELISA kits and antibodies in AntibodyShop have shown a satisfactory growth in the first half of 2015 of approximately 10%. Growth is expected to continue in the second half of 2015, both organically and as a result of greater impact from the 25 antibodies that were in-licensed in the first half of 2015.

As for the whole antibody portfolio, the new antibodies form the basis for the development of new products. The new products are related to immunodeficiency, an area in which BioPorto is already established via the MBL kit. BioPorto expects to launch the first immunodeficiency assays during the second half of 2015, so that they too can contribute to revenue in 2015.

In the end of June, the Antibody portfolio has been expanded with gRAD (Generic Rapid Assay Device), a generic strip test. gRAD is a patented lateral flow test system that makes it possible to develop and apply qualitative and quantitative rapid tests for the detection of, among other, viruses and bacteria in human and veterinary research use. The test has been in-licensed and is a good match for the portfolio of antibodies. The test is expected to become a very significant product in AntibodyShop portfolio.

## **Financial review**

### *Revenue*

BioPorto generated second-quarter revenue of DKK 5.8 million in 2015, compared to DKK 4.5 million in the year-earlier period, corresponding to a growth of 29%. The growth relates to increased sales of antibodies and ELISA kits of 13% and one-off revenue from a research collaboration regarding antibodies, which positively affects other products and licenses.

In the first half of 2015, BioPorto realizes a total revenue of DKK 9.9 million against DKK 9.2 million same period last year, corresponding to a growth of 8%. Sales development in the second quarter of 2015 for The NGAL Test<sup>™</sup> causes growth in the first half of 2015 to be less than expected.

#### *Operating costs and operating results*

Production costs amounted to DKK 2.7 million in the first half of 2015, which translates into a gross profit of DKK 7.2 million and a gross margin of 73% (2014: DKK 3.0 million and 68%).

Capacity costs amounted to DKK 15.7 million in the first half of 2015, against DKK 15.6 million in the year-earlier period. Costs of conducting the clinical trials with The NGAL Test<sup>™</sup> in the USA in the first half of 2015 amounts to DKK 2.1 million or a DKK 1.6 million increase in research and development costs compared with last year. On the other hand, other expenses were significantly reduced as a result of greater efficiency and fewer employees.

This brought the operating loss to DKK 8.5 million (2014: loss of DKK 9.3 million), which is slightly below expectations.

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

Net financials in the first half of 2015 were an expense of DKK 58,000, which brings the pre-tax loss for the first half of 2015 to DKK 8.5 million (2014: loss of DKK 9.3 million).

Recognition of a tax asset of DKK 1.4 million results in a net loss for the period of DKK 7.2 million (2014: loss of DKK 8.3 million).

#### *Balance sheet*

Total assets amounted to DKK 29.4 million at 30 June 2015 (2014: DKK 42.9 million). Non-current assets were at DKK 1.5 million (2014: 1.4 million), while inventories amounted to DKK 9.9 million (2014: DKK 10.3 million), and cash stood at DKK 18.0 million.

Equity amounted to DKK 20.2 million at 30 June 2015, against DKK 28.7 million at the beginning of the year. Liabilities at 30 June 2015 amounted to DKK 9.3 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 application for The NGAL Test<sup>™</sup> in the US market, while at the same time determine our US sales- and distribution strategy.
- Increase the number of routine users of NGAL at European clinics and centres for heart surgery and kidney transplants.
- Improving the preconditions for maintaining growth in sales of kits and antibodies, including the launch of gRAD and immunodeficiency assays.

#### **Guidance for 2015 revised**

BioPortos focus and initial work towards a US launch in 2016 means that the sales development in the short term will not be at the high end of the range. Thus, revenue in 2015 is now expected to be increased by 18-23% to DKK 22-23 million. against previously DKK 22-25 million. Revenue in the second half of 2015 will be positively affected by growth in sales of antibodies and ELISA kits as well as in sales of The NGAL Test<sup>™</sup>.

The revised revenue growth means that the operating profit is now expected to be realized with a loss of DKK 12 million against previously a loss of DKK 10 to 12 million. Operating costs will in the remainder of 2015 be

significantly reduced as a result of fewer employees and completion of clinical trials related to the US FDA application for The NGAL Test<sup>™</sup> in the first half of 2015.

Net profit is expected to be a loss of DKK 10 million against previously a loss of DKK 8-10 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:**

Peter Mørch Eriksen, CEO

Christina Thomsen, Investor Relations Manager

Tel: +45 4529 0000

E-mail: [investor@bioporto.com](mailto:investor@bioporto.com)

**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 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 – 30 June 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 30 June 2015 and of the results of the Group's operations and cash flows for the period 1 January 2015 – 30 June 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, 7 August 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**

	2015 2nd quarter DKK thousands	2014 2nd quarter DKK thousands	2015 6 months DKK thousands	2014 6 months DKK thousands
Net Revenues .....	5,804	4,485	9,933	9,236
Gross margin .....	4,539	3,086	7,234	6,272
<b>Earnings before interest and taxes .....</b>	<b>(4,038)</b>	<b>(5,682)</b>	<b>(8,465)</b>	<b>(9,306)</b>
<b>Earnings before taxes .....</b>	<b>(4,036)</b>	<b>(5,698)</b>	<b>(8,523)</b>	<b>(9,310)</b>
<b>Net profit/Comprehensive income, total .....</b>	<b>(3,271)</b>	<b>(4,645)</b>	<b>(7,168)</b>	<b>(8,257)</b>
	DKK	DKK	DKK	DKK
Earnings per share (eps/dps) .....	(0.03)	(0.04)	(0.06)	(0.07)

**Condensed balance sheet  
BioPorto Group**

<b>ASSETS</b>	2015	2014	2014
	June 30	Dec. 31	June 30
	DKK thousands	DKK thousands	DKK thousands
<b>Long-term assets</b>			
Intangible assets .....	334	199	243
Tangible assets .....	548	612	716
Financial assets.....	664	645	647
<b>Long-term assets, total .....</b>	<b>1,546</b>	<b>1,456</b>	<b>1,606</b>
<b>Short-term assets</b>			
Receivables and inventories .....	9,913	10,336	9,150
Cash resources .....	17,974	25,447	32,161
<b>Short-term assets, total .....</b>	<b>27,887</b>	<b>35,783</b>	<b>41,311</b>
<b>ASSETS, TOTAL .....</b>	<b>29,433</b>	<b>37,239</b>	<b>42,916</b>



**Condensed balance sheet  
BioPorto Group**

<b>LIABILITIES</b>	2015 June 30 DKK thousands	2014 Dec. 31 DKK thousands	2014 June 30 DKK thousands
<b>Equity</b>			
Capital stock .....	117,874	117,874	117,874
Other reserves .....	0	0	0
Reserve, share-based payment .....	648	648	897
Treasury stock .....	0	0	0
Retained income/loss .....	(98,359)	(89,836)	(85,416)
<b>Equity, total .....</b>	<b>20,163</b>	<b>28,686</b>	<b>33,355</b>
<b>Liabilities</b>			
<b>Long-term liabilities</b>			
Leasing.....	75	87	96
<b>Long-term liabilities, total .....</b>	<b>75</b>	<b>87</b>	<b>96</b>
<b>Short-term liabilities</b>			
Short-term segment of long-term liabilities.....	21	18	18
Suppliers of goods and services .....	1,888	1,199	1,645
Other debt .....	7,286	7,249	7,801
<b>Short-term liabilities, total .....</b>	<b>9,195</b>	<b>8,466</b>	<b>9,464</b>
<b>Liabilities, total .....</b>	<b>9,270</b>	<b>8,553</b>	<b>9,561</b>
<b>EQUITY AND LIABILITIES, TOTAL .....</b>	<b>29,433</b>	<b>37,239</b>	<b>42,916</b>

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

	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	(8,523)	<b>(8,523)</b>
<b>Equity, June 30, 2015.....</b>	<b>117,874</b>	<b>0</b>	<b>648</b>	<b>0</b>	<b>(98,359)</b>	<b>20,163</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	(8,257)	<b>(8,257)</b>
Transferred to "retained income".....	0	0	(769)	0	769	<b>0</b>
<b>Equity, June 30, 2014.....</b>	<b>117,874</b>	<b>0</b>	<b>897</b>	<b>0</b>	<b>(85,416)</b>	<b>33,355</b>

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

	2015 6 months DKK thousands	2014 6 months DKK thousands
Earnings before interest (EBIT) .....	(8,465)	(9,306)
Depreciation, amortization, write-downs and impairment ....	140	123
<b>Cash flow before change in working capital .....</b>	<b>(8,325)</b>	<b>(9,183)</b>
Change in working capital .....	1,149	(246)
<b>Cash flow from primary operations .....</b>	<b>(7,176)</b>	<b>(9,429)</b>
Interest income, included .....	115	41
Interest expenses, paid .....	(173)	(46)
Tax credit .....	0	0
<b>Cash flow from operating activities .....</b>	<b>(7,234)</b>	<b>(9,433)</b>
Purchase of intangible assets .....	(180)	(265)
Purchase of tangible assets .....	(50)	(542)
Purchase of financial assets .....	0	(393)
<b>Cash flow from investing activities .....</b>	<b>(230)</b>	<b>(1,200)</b>
Loans and credit facilities .....	0	0
Reduction of lease obligation.....	(9)	(8)
<b>Cash flow from financial activities .....</b>	<b>(9)</b>	<b>(8)</b>
<b>Cash flow for the period .....</b>	<b>(7,473)</b>	<b>(10,640)</b>
Cash balance at the beginning of the year .....	25,447	42,802
<b>Cash balance at the end of the period .....</b>	<b>17,974</b>	<b>32,161</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.

## Segments

The geographical dispersion of the net revenues is:	2015	2014
	6 months DKK thousands	6 months DKK thousands
Denmark .....	1,449	284
EU Member States .....	3,680	3,093
North America .....	3,724	4,699
Asia .....	714	796
Other .....	366	363
<b>Net revenues, total .....</b>	<b>9,933</b>	<b>9,236</b>

Product groups	2015	2014
	6 months DKK thousands	6 months DKK thousands
The NGAL test.....	1,302	1,261
ELISA Human NGAL kits.....	989	659
ELISA Amino NGAL kits.....	497	556
ELISA MBL kits.....	1,094	1,045
Antibodies.....	4,438	4,131
Other products and licenses.....	1,613	1,584
<b>Net revenues, total .....</b>	<b>9,236</b>	<b>9,236</b>