

**6 November 2015**  
**Announcement no. 22**

### **Interim financial report for Q3 2015 – the BioPorto Group**

---

#### **Submission of application to the FDA and successful rights issue**

- In September, following satisfactory clinical studies at leading hospitals in the US, BioPorto submitted a registration application to the FDA, regarding NGAL Test™. Approval is expected early 2016, and is a prerequisite for deployment of the test for clinical use in the US.
- The company's antibodies and assays for research use in the US are currently sold through distributors. With the anticipated FDA approval of The NGAL Test™, BioPorto has however initiated a significantly aggressive US sales and support strategy, which involves building a business base in the US for direct sales.
- In August, BioPorto completed a successful increase of the share capital through a fully subscribed private placement with gross proceeds of DKK 28.1 million. The proceeds will partly be used to finance the more aggressive US strategy, partly to an acceleration of the development and marketing of new products.
- In the third quarter of 2015, four new NGAL routine users were initiated, bringing the total number of routine users to 23.
- Negotiations with potential partners for the distribution and licensing agreements continue. If entered, the agreements will have financial effect no sooner than 2016 and not, as expected, in 2015.

#### **Continued improvement in results despite the focus on US preparations**

- The sale of The NGAL Test™ has not progressed as expected in 2015, largely due to preparations for market entry in the US. It is partly offset by an increase in sales of human NGAL ELISA kits, which underlines the interest for NGAL. In the first nine months of 2015, BioPorto's turnover amounts to DKK 14.6 million against DKK 13.8 million last year, corresponding to a moderate growth of 6%. Q3 revenue was DKK 4.7 million (2014: DKK 4.6 million), which is slightly lower than expected.
- The Group's cost focus is maintained and therefore EBIT totaled DKK -10.6 million (2014: DKK -12.4 million) with a net profit of DKK 8.9 million (2014: DKK -10.7 million).

#### **Guidance for 2015 adjusted**

- In 2015, revenue is expected to be DKK 21-22 million, representing a growth of 12-18% compared to 2014, against previous guidance of DKK 22-23 million.
- In 2015, an EBIT of DKK -13 million and a net result of DKK -11m is expected against previous guidance of EBIT of DKK -12 million. and net profit of DKK 10 million.

Peter Morch Eriksen, CEO comments: *"We have come far in the preparations for the launch of The NGAL Test™ in the US with the submission of the application to the FDA and a fully subscribed rights issue, which allows us to plan and implement a new, targeted US strategy. Growth in sales of The NGAL Test™ in Europe and of other products shows progress, but did not quite live up to expectations. The reason is in part due to resources focused on the strategic objectives. Beginning next year, the company will get the full effect of NGAL routine users and inlicensed antibodies. We have managed to keep costs at a minimum which means we can maintain our earnings expectations, apart from accelerated US investments."*

### Investor meeting

In connection with the release of the Q3 2015 interim report, BioPorto will arrange an investor meeting to be held on Friday 6 November 2015 at 3:00 pm at the company's address, Tuborg Havnevej 15, DK-2900 Hellerup, Denmark.

### Financial highlights

	2015 3rd quarter DKK thousands	2014 3rd quarter DKK thousands	2015 9 months DKK thousands	2014 9 months DKK thousands	2014 12 months DKK thousands
Net revenues .....	4,684	4,571	14,617	13,807	18,705
Net income/loss, ordinary operating act (EBIT) .....	(2,108)	(3,074)	(10,573)	(12,380)	(15,256)
Income/loss from net financials .....	(159)	145	(217)	141	159
Earnings before tax .....	(2,267)	(2,929)	(10,790)	(12,239)	(15,097)
Net income/loss for the period .....	(1,710)	(2,468)	(8,877)	(10,725)	(12,926)
Long-term assets .....	1,476	1,529	1,476	1,529	1,456
Short-term assets .....	53,727	39,688	53,727	39,688	35,783
Total assets .....	55,203	41,216	55,203	41,216	37,239
Capital stock .....	129,599	117,874	129,599	117,874	117,874
Equity .....	46,353	32,137	46,353	32,137	28,686
Long-term liabilities .....	70	92	70	92	87
Short-term liabilities .....	8,780	8,987	8,780	8,987	8,466
Total liabilities .....	55,203	41,216	55,203	41,216	37,239
Cash flow from by operations .....	(5,272)	(2,239)	(10,594)	(11,672)	(16,138)
Cash flow from investing, net .....	0	0	(230)	(1,200)	(1,199)
Of which invested in property, plant and equipment ...	0	0	(50)	(542)	(542)
Cash flow from financing .....	27,805	(4)	26,529	(12)	(18)
Total cash flow .....	22,533	(2,243)	15,705	(12,884)	(17,355)
Revenue growth .....	2%	-8%	6%	13%	13%
Gross margin ratio .....	79%	75%	75%	70%	71%
Operating margin .....	-45%	-67%	-72%	-90%	-82%
Equity interest (equity ratio) .....	84%	78%	84%	78%	77%
Return on equity .....	Negativ	Negativ	Negativ	Negativ	Negativ
Average no. of employees .....	22	24	23	24	24
Average no. of shares (1,000) .....	129,586	117,861	129,586	117,861	117,874
Earnings per share (EPS) DKK .....	(0.01)	(0.02)	(0.08)	(0.09)	(0.11)
Equity value per share, closing, DKK .....	0.36	0.27	0.36	0.27	0.24
Listed price, closing, DKK .....	2.66	1.84	2.66	1.84	1.69

**Application on The NGAL Test™ pending with the FDA**

In September, BioPorto submitted the registration application to the US Food and Drug Administration for approval of The NGAL Test™. The submission was based on finalized data from the clinical study in the US that satisfactorily supports the application claiming the use of The NGAL Test™ in the diagnosis of acute kidney injury (AKI).

After submission, BioPorto, in consultation with the FDA, decided to switch to a De Novo request instead of the original 510 (k) request. Regardless of classification, the resulting approval is the same. It is not unusual that the FDA recommends re-classification, and as De Novo is intended for low-risk medical equipment, BioPorto expects no significant changes in the process by the FDA. It is therefore expected that the FDA approval can be obtained at the beginning of the 2016.

**New US strategy and increase of share capital**

In the autumn of 2015, BioPorto established a targeted and direct market entry strategy for The NGAL Test™ in the US. The company is currently working on the establishment of a US business base with sales and support function with 5-7 American employees in the initial phase. The establishment has been initiated, and in 2015, the cost in the US is expected be DKK 1 million, which is included in the adjusted profit forecasts. Sales efforts will be directed initially towards established contacts and building new partnerships, a total of 20-30 sites in selected geographies.

To support the establishment, BioPorto concluded a share issue on August 31, 2015 directed at a limited number of institutional and financial investors. The issue was fully subscribed and a total of 11,724,750 new shares of DKK 1.00 were issued against payment of DKK 2.40 per share of DKK 1.00, corresponding to gross proceeds of DKK 28.1 million. The new shares correspond to 9.9% of BioPorto's registered share capital before the capital increase. After registration of the new shares, BioPorto's nominal share capital amounts to DKK 129,598,960 consisting of 129,598,960 shares of DKK 1.00.

**New NGAL routine users, but still modest sales**

With the addition of four new routine users in Q3 2015, the number of routine users of The NGAL Test™ end September is 23. The aim is still to have a minimum of 25 routine users by the end of 2015, which provides a good foundation for the further dissemination.

The test is set up in the new clinics equipment, but has not contributed significantly to the sales of The NGAL Test™ which in the third quarter of 2015 totals DKK 0.6 million, which is on par with the same period last year. The revenue from The NGAL Test™ in the first nine months of 2015 amounts to DKK 2 million which is in line with the same period last year. However, there has been an increase of 66% in the sales of NGAL ELISA kits in Q3 2015, which is a precursor to the implementation of the automated The NGAL Test™, and thus emphasizes the interest in NGAL. However, an increased interest and acceptance of NGAL as a biomarker for AKI in Europe is expected only after an introduction and widespread use of The NGAL Test™ has taken place in the US.

The growth in sales of The NGAL Test™ in Europe and the company's other products are slightly below previous estimates. The business focus and resources have been directed towards the establishment in the US, which has had an impact on the daily sales efforts. Sales efforts in existing markets are fully focused in the fourth quarter of 2015, and with current projects this last quarter is expected to surpasses recent quarters in terms of sales.

**Distribution and licensing agreement negotiation continues**

Negotiations with potential partners for the distribution and licensing agreements continue. If entered, the agreements will have financial effect no sooner than 2016 and not, as expected, in 2015.

## **Financial review**

### *Revenue*

BioPorto generated third-quarter revenue of DKK 4.7 million in 2015, compared to DKK 4.6 million in the year-earlier period. In the first nine months of 2015, BioPorto realizes a total revenue of DKK 14.6 million against DKK 13.8 million same period last year, corresponding to a growth of 5.9%. Sales development for The NGAL Test™ causes growth in the nine months of 2015 to be less than expected.

### *Operating costs and operating results*

Production costs amounted to DKK 3.7 million in the first nine months of 2015, which translates into a gross profit of DKK 10.9 million and a gross margin of 74% (2014: DKK 4.1 million and 70%).

Capacity costs amounted to DKK 21.5 million in the first nine months of 2015, against DKK 22.1 million in the year-earlier period. Costs of conducting the clinical trials with The NGAL Test™ 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 10.6 million (2014: loss of DKK 12.4 million), which is slightly below expectations.

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

Net financials in the first nine months of 2015 were an expense of DKK 217,000, which brings the pre-tax loss for the first nine months of 2015 to DKK 10.8 million (2014: loss of DKK 12.2 million).

Recognition of a tax asset of DKK 1.9 million results in a net loss for the period of DKK 8.9 million (2014: loss of DKK 10.7 million).

### *Balance sheet*

Total assets amounted to DKK 55.2 million at 30 September 2015 (2014: DKK 41.2 million). Non-current assets were at DKK 1.5 million (2014: 1.5 million), while inventories amounted to DKK 12.6 million (2014: DKK 10.3 million), and cash stood at DKK 41.2 million.

Equity amounted to DKK 46.4 million at 30 September 2015, against DKK 28.7 million at the beginning of the year. Liabilities at 30 September 2015 amounted to DKK 8.9 million, consisting primarily of trade payables.

## **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 sales and establishing a base in the US**

The management priorities for the remaining part of 2015 comprise:

- Increase sales of The NGAL Test™ and 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.
- Establishment of US business base and preparations for launch of The NGAL Test™ upon FDA approval.
- Support the application process for The NGAL Test™ with the FDA in the US.

**Guidance for 2015**

While the strategic development of the company is progressing as planned, sales of existing products in existing markets performed slightly below the target. As a consequence, expectations are adjusted so that the turnover in 2015 is now expected to increase by 12-18% compared with 2014 to DKK 21-22 million from DKK 22-23 million.

Operating profit is expected to be realized with a loss of DKK 13 million against previously a loss of DKK 12 million. Net profit is expected to be a loss of DKK 11 million compared to previously a loss of DKK 10 million. The result is affected by the initial investment in the US of approximately DKK 1 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 September 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 September 2015 and of the results of the Group's operations and cash flows for the period 1 January 2015 – 30 September 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, 6 November 2015

**Management Board:**

---

Peter Mørch Eriksen  
CEO

**Board of Directors:**

---

Thomas Magnussen  
Chairman

---

Torben A. Nielsen  
Vice Chairman

---

Roar Bjørk Seeger

---

Jan Kuhlmann Andersen

**Condensed statement of comprehensive income  
BioPorto Group**

	2015 3rd quarter DKK thousands	2014 3rd quarter DKK thousands	2015 9 months DKK thousands	2014 9 months DKK thousands
Net Revenues .....	4,684	4,571	14,617	13,807
Gross profit .....	3,713	3,429	10,947	9,701
<b>Earnings before interest and taxes .....</b>	<b>(2,108)</b>	<b>(3,074)</b>	<b>(10,573)</b>	<b>(12,380)</b>
<b>Earnings before taxes .....</b>	<b>(2,267)</b>	<b>(2,929)</b>	<b>(10,790)</b>	<b>(12,239)</b>
<b>Net profit/Comprehensive income, total .....</b>	<b>(1,710)</b>	<b>(2,468)</b>	<b>(8,877)</b>	<b>(10,725)</b>
	DKK	DKK	DKK	DKK
Earnings per share (eps/dps) .....	(0.01)	(0.02)	(0.08)	(0.09)

**Condensed balance sheet  
BioPorto Group**

<b>ASSETS</b>	2015 Sep. 30	2014 Dec. 31	2014 Sep. 30
	DKK thousands	DKK thousands	DKK thousands
<b>Long-term assets</b>			
Intangible assets .....	313	199	221
Tangible assets .....	499	612	661
Financial assets.....	664	645	647
<b>Long-term assets, total .....</b>	<b>1,476</b>	<b>1,456</b>	<b>1,529</b>
<b>Short-term assets</b>			
Receivables and inventories .....	12,575	10,336	9,769
Cash resources .....	41,152	25,447	29,918
<b>Short-term assets, total .....</b>	<b>53,727</b>	<b>35,783</b>	<b>39,688</b>
<b>ASSETS, TOTAL .....</b>	<b>55,203</b>	<b>37,239</b>	<b>41,216</b>



**Condensed balance sheet  
BioPorto Group**

<b>LIABILITIES</b>	2015 Sep. 30 DKK thousands	2014 Dec. 31 DKK thousands	2014 Sep. 30 DKK thousands
<b>Equity</b>			
Capital stock .....	129,599	117,874	117,874
Other reserves .....	0	0	0
Reserve, share-based payment .....	648	648	897
Treasury stock .....	0	0	0
Retained income/loss .....	(83,894)	(89,836)	(86,634)
<b>Equity, total .....</b>	<b>46,353</b>	<b>28,686</b>	<b>32,137</b>
<b>Liabilities</b>			
<b>Long-term liabilities</b>			
Leasing.....	70	87	92
<b>Long-term liabilities, total .....</b>	<b>70</b>	<b>87</b>	<b>92</b>
<b>Short-term liabilities</b>			
Short-term segment of long-term liabilities.....	21	18	18
Suppliers of goods and services .....	2,017	1,199	878
Other debt .....	6,742	7,249	8,091
<b>Short-term liabilities, total .....</b>	<b>8,780</b>	<b>8,466</b>	<b>8,987</b>
<b>Liabilities, total .....</b>	<b>8,850</b>	<b>8,553</b>	<b>9,079</b>
<b>EQUITY AND LIABILITIES, TOTAL .....</b>	<b>55,203</b>	<b>37,239</b>	<b>41,216</b>

## Statement of changes in equity BioPorto Group

	Capital stock	Treasury stock	Share premium	Share-based payment	Other reserves	Retained income/loss	Total
	DKK thousands	DKK thousands	DKK thousands	DKK thousands	DKK thousands	DKK thousands	DKK thousands
Equity, January 1, 2015.....	117,874	0	0	648	0	(89,836)	<b>28,686</b>
Comprehensive income for the period.....	0	0	0	0	0	(8,877)	<b>(8,877)</b>
Share emission.....	11,725	0	16,415	0	0	0	<b>28,140</b>
Emission costs.....	0	0	(1,596)	0	0	0	<b>(1,596)</b>
Transferred to "retained income".....	0	0	(14,819)	0	0	14,819	<b>0</b>
<b>Equity, September 30, 2015.....</b>	<b>129,599</b>	<b>0</b>	<b>0</b>	<b>648</b>	<b>0</b>	<b>(83,894)</b>	<b>46,353</b>

	Capital stock	Treasury stock	Share premium	Share-based payment	Other reserves	Retained income/loss	Total
	DKK thousands	DKK thousands	DKK thousands	DKK thousands	DKK thousands	DKK thousands	DKK thousands
Equity, January 1, 2014.....	117,874	0	0	1,666	0	(76,678)	<b>42,862</b>
Comprehensive income for the period.....	0	0	0	0	0	(10,725)	<b>(10,725)</b>
Transferred to "retained income".....	0	0	0	(769)	0	769	<b>0</b>
<b>Equity, September 30, 2014.....</b>	<b>117,874</b>	<b>0</b>	<b>0</b>	<b>897</b>	<b>0</b>	<b>(86,634)</b>	<b>32,137</b>

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

	2015 9 months DKK thousands	2014 9 months DKK thousands
Earnings before interest (EBIT) .....	(10,573)	(12,380)
Depreciation, amortization, write-downs and impairment ....	212	199
<b>Cash flow before change in working capital .....</b>	<b>(10,361)</b>	<b>(12,180)</b>
Change in working capital .....	(16)	368
<b>Cash flow from primary operations .....</b>	<b>(10,377)</b>	<b>(11,812)</b>
Interest income, included .....	254	210
Interest expenses, paid .....	(471)	(69)
Tax credit .....	<b>(10,594)</b>	<b>(11,672)</b>
<b>Cash flow from operating activities .....</b>	<b>(180)</b>	<b>(265)</b>
Purchase of intangible assets .....	(50)	(542)
Purchase of tangible assets .....	0	(393)
Purchase of financial assets .....	<b>(230)</b>	<b>(1,200)</b>
<b>Cash flow from investing activities .....</b>	<b>0</b>	<b>0</b>
Loans and credit facilities .....	26,544	0
Reduction of lease obligation.....	(15)	(12)
<b>Cash flow from financial activities .....</b>	<b>26,529</b>	<b>(12)</b>
<b>Cash flow for the period .....</b>	<b>15,705</b>	<b>(12,884)</b>
Cash balance at the beginning of the year .....	25,447	42,802
<b>Cash balance at the end of the period .....</b>	<b>41,152</b>	<b>29,918</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
	9 months DKK thousands	9 months DKK thousands
Denmark .....	1,504	373
EU Member States .....	5,062	5,152
North America .....	5,583	6,481
Asia .....	1,268	1,303
Other .....	1,199	497
<b>Net revenues, total .....</b>	<b>14,616</b>	<b>13,807</b>

Product groups	2015	2014
	9 months DKK thousands	9 months DKK thousands
The NGAL test.....	1,907	1,903
ELISA Human NGAL kits.....	1,951	1,172
ELISA Amino NGAL kits.....	672	928
ELISA MBL kits.....	1,871	1,584
Antibodies.....	6,317	6,392
Other products and licenses.....	1,898	1,826
<b>Net revenues, total .....</b>	<b>14,616</b>	<b>13,807</b>