Interim Report

First half of 2019, BioPorto Group

August 15, 2019
Announcement no. 15

bioporto

BioPorto A/S
Tuborg Havnevej 15
DK-2900 Hellerup
CVR DK-17500317

Highlights

Additional Information request from FDA on the pediatric application for The NGAL Test™ postpones clearance

In mid-July 2019, BioPorto received an additional information (AI) request from the U.S. Food & Drug Administration (FDA) on its May 2019 application for clearance of The NGAL Test™ for risk assessment of acute kidney injury (AKI) in children under the age of 22.

BioPorto has initiated a dialogue with the FDA to clarify the questions in the AI request and to support its application. Based on the progression of this dialogue, BioPorto may initiate analysis of additional retrospective clinical samples in cooperation with Cincinnati Children's Hospital and other partner hospitals. The Company expects to submit a new application package to the FDA during the fourth quarter of 2019.

Enrollment of U.S. patients for The NGAL Test's clinical study in adults continues as planned

In the second quarter of 2019 BioPorto continued enrollment of patients at three leading academic medical centers to supplement its clinical trial for The NGAL Test in adults.

The final application for risk assessment of The NGAL Test in adults is expected to be submitted to the FDA in Q4 2019.

U.S. organization expanded

To prepare for U.S. launch, build awareness of AKI and support increased study of NGAL, BioPorto has initiated commercial expansion in the U.S.

In the second quarter of 2019, BioPorto appointed Amy Winslow as President for its U.S. subsidiary, BioPorto Diagnostics, Inc. to lead the Company's commercial organization. In addition, Dr. Christopher Bird has recently joined as BioPorto's first Chief Medical Officer (CMO). Both Amy and Chris are members of BioPorto's Corporate Management.

Successful share capital increase completed

In June 2019, BioPorto initiated a private placement cash issue of 9,256,577 new shares at nominally DKK 1 each equivalent to 5.59% of BioPorto's registered share capital prior to the capital increase. The subscription price was DKK 3.97 per share. The Board of Directors had received binding advance subscription commitments for the entire offering from existing shareholders and new investors, representing both domestic and international interests. The fully subscribed and successfully completed private placement was concluded in July 2019 and yielded gross proceeds of DKK 36.7 million.

Growth in second quarter 2019 revenue driven by solid performance in NGAL sales and antibodies

BioPorto's revenue in the second quarter of 2019 grew by 10% to DKK 7.8 million compared to DKK 7.2 million last year. Two components drove growth: increased U.S. revenues from NGAL, up 43% in the quarter, and sales of antibodies which were positively affected by larger bulk orders.

BioPorto's operating loss before interest and tax (EBIT) for the second quarter of 2019 was DKK 16.5 million, compared to a loss of DKK 10.0 million in the same period of 2018. Investment in the U.S. organization and the full-year effects of 2018 hiring were the main reasons for the change.

Revised sales and EBIT guidance for 2019

Based on the postponement of the anticipated FDA clearance of the pediatric indication for The NGAL Test, BioPorto has revised its expected revenue in the financial year 2019 from approximately DKK 40 million to approximately DKK 32 million. The revised revenue expectation corresponds to a growth rate of 23% over 2018.

The operating loss (EBIT) in the same period has been revised from a loss of approximately DKK 45 million to a loss of approximately DKK 65 million. The EBIT is primarily impacted by the reduced revenue, investment in the U.S. organization and extra costs for the pediatric clearance of NGAL due to the reported delay.

Peter M. Eriksen, CEO commented: "Following an intense second quarter where we strengthened our U.S. organization, completed a successful share issue, increased NGAL sales and submitted the U.S. pediatric application of The NGAL Test, we received questions from the FDA regarding our application in mid-July. The main questions were related to the test's sensitivity. Together with a group of nephrologists and intensivists who are experts in the management of children with AKI, we have initiated a dialogue with the FDA to further describe the current clinical paradigm and the medical implications of our statistics, which we collectively believe represent an important advancement over the current standard of care. While the clearance and commercialization of NGAL has been delayed from our initial expectation, I remain very confident that we will succeed in introducing a new tool to advance the early detection of AKI risk."

Extraordinary General Meeting and Investor meeting

The Board of Directors of BioPorto will convene an extraordinary general meeting (EGM) in order to elect two new members to its Board. Proposed are: Christopher Lindop, a U.S. citizen with considerable experience in management of U.S. listed healthcare companies, including expertise in finance and reporting, corporate governance, mergers & acquisitions, funding, and strategy development; and Michael Singer, a U.S. citizen who is an entrepreneurial M.D./Ph.D. with significant experience in designing and executing pre-clinical and clinical development processes and successfully building biotech and healthcare companies.

The EGM will be held on August 15, 2019 at 2:00 PM (CET) at BioPorto's address Tuborg Havnevej 15 st., 2900 Hellerup, Denmark.

Following the EGM and at the same venue, BioPorto will in connection with the release of the interim report for first half of 2019 host an investor meeting at 3:00 PM (CET). To attend the investor meeting, please sign up at investor@bioporto.com.

Financial highlights

	2019 2nd quarter DKK million	2018 2nd quarter DKK million	2019 6 months DKK million	2018 6 months DKK million	2018 12 months DKK million
Revenue	7.8	7.1	13.3	11.8	26.0
Production costs	(2.6)	(2.2)	(4.9)	(3.6)	(8.2)
Sales and marketing costs	(9.3)	(5.2)	(16.6)	(10.2)	(20.9)
Research and development costs	(5.4)	(5.9)	(9.6)	(11.9)	(18.7)
Administrative costs	(7.0)	(3.8)	(16.0)	(8.6)	(20.0)
Operating profit/loss (EBIT)	(16.5)	(10.0)	(33.7)	(22.5)	(41.8)
Net financials	(0.2)	0.1	(0.3)	0.2	0.2
Operating profit/loss before tax	(16.8)	(9.9)	(33.9)	(22.4)	(41.6)
Profit/loss for the period	(15.8)	(8.6)	(32.2)	(19.8)	(38.0)
Total comprehensive income	(16.0)	(8.6)	(32.2)	(19.9)	(38.3)
Non-current assets			7.7	2.9	3.6
Current assets			68.7	42.5	62.6
Total assets			76.4	45.5	66.2
Equity			61.3	37.1	56.2
Non-current liabilities			1.8	0.7	0.8
Current liabilities			13.3	7.6	9.2
Total equity and liabilities			76.4	45.5	66.2
Cash flows from operating activities			(29.5)	(23.9)	(38.0)
Cash flows from investing activities, net			(0.5)	(0.5)	(1.5)
Of which investment in property, plant and equipment			(0.0)	(0.5)	(1.4)
Cash flows from financing activities			34.7	(0.2)	39.1
Total cash flows			4.7	(24.6)	(0.4)
Revenue growth	10%	8%	14%	-5%	3%
Gross margin	66%	70%	64%	70%	69%
Equity ratio (solvency)	80%	82%	80%	82%	85%
Average number of employees	37	27	34	26	28
Number of shares by the end of the period (1,000)	174,944	155,510	174,944	155,510	165,688
Earnings per share (EPS), DKK	(0.10)	(0.06)	(0.19)	0.13	0.24
Net asset value per share, period-end, DKK	0.35	0.24	0.35	0.24	0.34
Share price, period-end, DKK	3.91	3.19	3.91	2.68	3.50

Management review

FDA application for pediatric use of The NGAL Test to be re-submitted in the fourth quarter of 2019

In May 2019, BioPorto submitted an application to the FDA for regulatory clearance of The NGAL Test for risk assessment of AKI in critically ill children under the age of 22. The application was based on a retrospective set of samples of urinary NGAL originally obtained as part of the multinational AWARE study conducted in 2014.

For the application, BioPorto re-tested a subset of the original samples collected from 4,683 patients at 32 pediatric Intensive Care Units (ICUs) across Asia, Australia, Europe and North America with The NGAL Test, to demonstrate it's ability to predict the risk of patients developing moderate to severe AKI. The NGAL Test showed a sensitivity of 65.0% and specificity of 81.8% with a negative predictive value of 95.4%.

In mid-July 2019, BioPorto received an AI request from the FDA, primarily concerning the clinical data and collection of retrospective samples, which was conducted with assistance from kidney specialists at Cincinnati Children's Hospital in the U.S. As part of its response, the FDA questioned whether the reported sensitivity was high enough to be clinically relevant.

In response, BioPorto has initiated a dialogue with the FDA to clarify the questions and potential need for further clinical data. In this dialogue, BioPorto is being supported by leading clinical experts who are helping to describe the utility of The NGAL Test in improving the risk assessment of AKI in critically ill children.

Depending on the progression of the dialogue with the FDA, BioPorto will in cooperation with Cincinnati Children's Hospital and other leading U.S. pediatric hospitals initiate collection of additional retrospective samples and expects to submit an expanded application package to the FDA during the fourth quarter of 2019.

Enrollment of patients for The NGAL Test clinical study in adults in the U.S. continues as planned

In the second quarter of 2019 BioPorto has continued to enroll patients to supplement the clinical data in its application to the FDA for The NGAL Test in adult populations.

The supplemental study aims to collect samples from critically ill adults with AKI and is expected to include 150-200 patients. Results from these individuals will be added the data collected in 2017 and 2018.

The final application for risk assessment of The NGAL Test in adults is expected to be submitted to the FDA in Q4 2019. Once BioPorto receives clearance of this application the Company will commence a full-scale commercialization through its own salesforce and its distribution partners, Roche and Siemens.

New U.S. government support for improving kidney health

Better management of AKI in critically ill patients represents a substantial unmet medical need in the U.S. and around the globe. It is well understood that better diagnostic and therapeutic options for kidney disease have the potential to improve both patient care and healthcare economics.

In recent years, BioPorto has invested substantially in building awareness of NGAL as an early biomarker for AKI. Much of this effort has been focused in the U.S., the global market leader in diagnostics. U.S. clinical experts, including intensivists and nephrologists, believe the NGAL biomarker can have a significant impact on AKI prevention and management strategies.

The need to improve kidney health gained momentum in July when President Donald J. Trump signed an executive order launching a kidney health initiative to improve the lives of Americans suffering from kidney disease. Through a series of initiatives, the U.S. government seeks to prevent kidney failure through better diagnosis, treatment, and preventative care.

The executive order and heightened awareness of the need for better management of kidney disorder is expected to add momentum to BioPorto's efforts to bring attention to its NGAL platform. They also support the Company's strategy of enabling healthcare practitioners to improve the standard of care for AKI management.

U.S. organization expanded to prepare for commercial launch and future expansion

To expand its foothold in the U.S. prior to regulatory clearance and commercial launch of The NGAL Test, BioPorto has strengthened its U.S. organization in the first half of 2019.

In April 2019, Amy Winslow, former President and CEO of Magellan Diagnostics, was appointed as President for BioPorto's U.S. subsidiary, BioPorto Diagnostics, Inc. and as a member of BioPorto's Corporate Management. Amy is responsible for building and leading the U.S. organization as BioPorto prepares to launch The NGAL Test™ for clinical use following expected clearance by the FDA.

In June 2019, BioPorto announced the appointment of Christopher Bird, former Head of the North American Medical and Scientific Affairs organization for Roche Inc., as its new Chief Medical Officer (CMO) and as a member of BioPorto's Corporate Management. Christopher will be responsible for building, executing and overseeing BioPorto's diagnostic product development. He will be an important contributor to future clinical regulatory applications and will be responsible for the dialogue with BioPorto's scientific advisory board.

U.S. NGAL revenue increased 43% in the second quarter of 2019

BioPorto is focusing on converting the growing interest in its platform to increased NGAL revenue in the U.S. In the second quarter of 2019, NGAL related U.S. sales increased by 43% year-on-year, and total global NGAL sales were up 17% to DKK 3.8 million. Year-to-date, U.S. revenue from NGAL increased by 60% compared to last year, and total NGAL revenue grew 23%.

Bulk orders continue to positively impact antibody sales

Revenue from sales of antibodies in the first half of 2019 was DKK 5.3 million, up from DKK 4.3 million last year. For the first half of 2019, antibody revenue increased by 23%, driven by larger bulk orders.

Share capital increase with proceeds of DKK 36.7 million

In June 2019, BioPorto completed a private placement cash issue. The proceeds will support the FDA application processes, and enable the Company to continue preparing for U.S. commercialization of the tests, support growing sales, and strengthen the company's overall liquidity

In total, 9,256,577 new shares at nominally DKK 1 each equivalent to 5.59% of BioPorto's registered share capital prior to the capital increase, were offered at a subscription price of DKK 3.97 per share. The Board of Directors had received binding advance subscription commitments for the entire offering of new shares from existing shareholders and new investors, both domestic and international.

The fully subscribed and successful private placement yielded gross proceeds of DKK 36.7 million. Following the issue, BioPorto's share capital totaled DKK 174,944,375 divided into 174,944,375 shares of nominally DKK 1 each carrying one vote.

Events after the reporting period

At the Board of Directors meeting held on August 15, 2019 the Board of Directors elected to utilize the remaining authorization to issue warrants. Accordingly BioPorto will issue 1,500,000 new warrants to key employees in the Company's U.S. organization. This will support the company's long-term goals and establish a performance-based remuneration that will support the Company's and its shareholders' interests.

Financial review

Income statement

The financial review is based on the Group's consolidated financial information for the period ended June 30, 2019, with comparative results for June 30, 2018 in brackets.

In the second quarter of 2019 revenues totaled DKK 7.8 million (DKK 7.1 million) and for the first six months totaled DKK 13.3 million (DKK 11.8 million). Earnings before interest and taxes (EBIT) showed a loss of DKK 16.5 million (DKK 10.0 million) in the second quarter of 2019, and in the first six months of 2019 showed a loss of DKK 33.7 million (DKK 22.5 million). The cash position as of June 30, 2019 equaled DKK 51.4 million (DKK 22.5 million).

Revenue

Revenue in the second quarter of 2019 was DKK 7.8 million (DKK 7.1 million). For the first six months of 2019 revenue totaled DKK 13.3 million (DKK 11.8 million).

In the second quarter of 2019 NGAL revenue totaled DKK 3.8 million (DKK 3.3 million) and for the first six months of 2019 totaled DKK 5.1 million (DKK 4.1 million). Revenue in the second quarter of 2019 comprised DKK 0.7 million (DKK 0.9 million) from RUO sales in the U.S., DKK 1.9 million (DKK 1.9 million) from sales in the EU and the rest of the world and DKK 1.2 million (DKK 0.5 million) in NGAL related fees and licenses.

For the first six months of 2019 revenue from The NGAL test comprised DKK 1.6 million (DKK 1.3 million) from RUO sales in the U.S., DKK 2.3 million (DKK 2.3 million) from sales in the EU and the rest of the world and DKK 1.2 million (DKK 0.5 million) in NGAL related fees and licenses.

Revenue from the sale of antibodies amounted to DKK 2.4 million (DKK 2.2 million) in the second quarter of 2019. For the first six months of 2019 revenue from sale of antibodies was DKK 5.3 million (DKK 4.3 million). This growth was driven by bulk orders, part of which was due to delayed sales from 2018.

Revenues from the sale of ELISA kits totaled DKK 1.4 million (DKK 1.6 million) during the second quarter of 2019, and DKK 2.5 million (DKK 3.0 million) for the first six months of 2019. The decrease was due to worsened market conditions and altered buying patterns.

Figure 1. Revenue by quarter (DKK million)

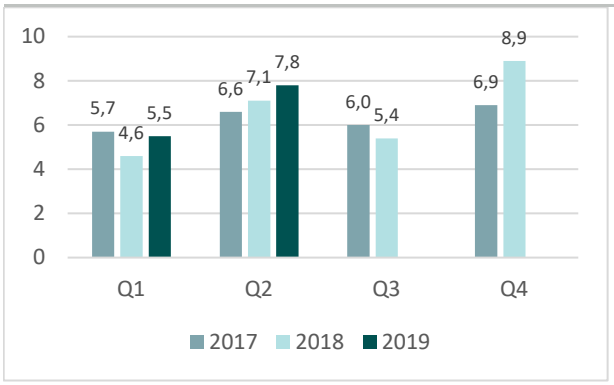
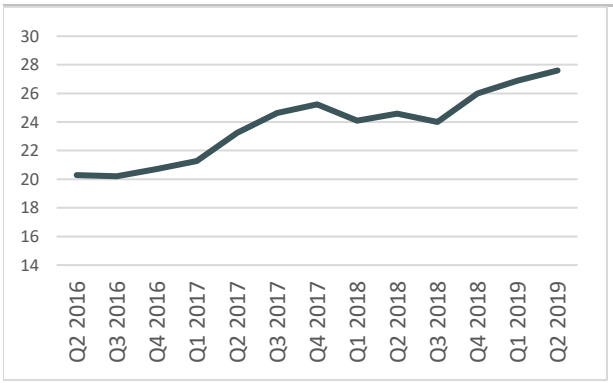


Figure 2. Revenue, LTM (DKK million)



Production costs

Production costs in the second quarter of 2019 were DKK 2.6 million (DKK 2.2 million) bringing the gross profit for the quarter to DKK 5.2 million (DKK 5.0 million) and the gross margin for the quarter to 66% (70%).

For the first six months of 2019 production costs totaled DKK 4.9 million (DKK 3.6 million) bringing the gross profit for first six months of 2019 to DKK 8.5 million (DKK 8.2 million) and the gross margin for the first six months of 2019 to 64% (70%).

The increase in production costs is primarily due to increased staff related costs totaling DKK 0.6 million for the first six months of 2019.

Sales and marketing costs

Sales and marketing costs totaled DKK 9.3 million (DKK 5.2 million) in the second quarter of 2019 and DKK 16.6 million (DKK 10.2 million) for the first six months of 2019. The increase was primarily as a result of growth in the U.S. organization, which for the first six months of 2019 resulted in additional staff-related costs of DKK 5.1 million, increased consulting expenses of DKK 0.8 million and increased travel spend of DKK 0.8 million.

Research and development costs

Research and development costs in the second quarter of 2019 equaled DKK 5.4 million (DKK 5.9 million) and for the first six months of 2019 were DKK 9.6 million (DKK 11.9 million). For the first six months of 2019 clinical study costs were reduced by DKK 3.3 million as activities for the NGAL pediatric study and the additional enrollment of patients for the NGAL adult study were lower than the activities for the NGAL adult study completed during the same period in 2018.

Administrative costs

Administrative costs in the second quarter of 2019 totaled DKK 7.0 million (DKK 3.8 million) and for the first six months of 2019 totaled DKK 16.0 million (DKK 8.6 million). For the first six months of 2019 staff-related costs increased by DKK 4.5 million, consulting expense increased by DKK 1.4 million and legal fees increased DKK 0.8 million compared to same period in 2018.

Financials net

Financial net was an expense of DKK 0.2 million (income of DKK 0.1 million) for the second quarter of 2019. For the first six months of 2019 financial net was an expense of DKK 0.3 million (income of DKK 0.2 million).

Tax on income for the year

In the second quarter of 2019 tax on income for the year was an income of DKK 1.0 million (income of DKK 1.3 million), and for the first six months of 2019 an income of DKK 1.7 million (income of DKK 2.6 million). Tax on income for the year is primarily related to refunded tax losses originating from research and development costs.

Balance sheet

The balance sheet total was DKK 76.4 million as of June 30, 2019 (DKK 45.5 million).

Assets

Intangible assets were DKK 1.7 million (DKK 1.5 million). The Company has no capitalized research and development costs.

Fixtures and fittings, tools and equipment equaled DKK 1.3 million (DKK 0.7 million). The increase is primarily due to investment in a new lab room and lab instruments in 2018 partly offset by depreciation.

Rights-to-use assets have been recognized starting January 1, 2019 as part of applying IFRS 16. Rights-to-use assets consists of the group leases of office space and vehicles and totaled DKK 4.0 million as of June 30, 2019. No right-to-use assets were recognized in 2018.

Financial assets equaled DKK 0.8 million (DKK 0.8 million) and consist of deposits.

Inventory was DKK 3.7 million (DKK 3.9 million) and consists primarily of finished goods.

Total receivables totaled DKK 13.6 million (DKK 16.1 million), of which trade receivables were DKK 7.2 million (DKK 7.3 million).

Income tax receivables totaled DKK 5.4 million (DKK 7.4 million) and other receivables DKK 1.1 million (DKK 1.4 million).

As of June 30, 2019, BioPorto's cash position was DKK 51.4 million (DKK 22.5 million) and is primarily invested in deposit accounts with two Nordic banks.

Equity

After transfer of the loss of the period, equity stood at DKK 61.3 million (DKK 37.1 million).

Liabilities

Non-current liabilities equaled DKK 1.8 million (DKK 0.7 million). The increase is due to lease obligations recognized as of January 1, 2019 as part of applying IFRS 16.

Current liabilities were DKK 13.3 million (DKK 7.6 million) of which trade payables were DKK 2.4 million (DKK 3.9 million) and other payables were DKK 8.1 million (DKK 3.6 million).

Cash flow statement

Net cash expenditure from operating activities amounted to DKK 29.5 million (DKK 23.9 million), the increase was driven by the net loss from the first six months and partly offset by a decrease in working capital.

Net cash spend on investing activities was DKK 0.5 million (DKK 0.5 million) of which the majority was investment in new software. In 2018 investments were primarily in property, plant and equipment.

Net cash provided from financing activities totaled DKK 34.7 million (spend of DKK 0.2 million) primarily related to proceeds from share capital increase.

The net cash flow for the first six month of 2019 was positive by DKK 4.7 million (negative by DKK 24.6 million).

Accounting policies

The interim report for the first six months of 2019 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 six months of 2019 follows the same accounting policies as the annual report for 2018, except for new accounting standards and interpretations (IFRSs) endorsed by the EU effective for the accounting period beginning on January 1, 2019. This includes IFRS 16 'Leases' which was implemented using the modified retrospective approach on January 1, 2019. The implementation has not affected comparatives.

At initial recognition, right-of-use assets are measured as an amount equal to the lease liability, which is measured at the present value of future lease payments. The lease liability is measured using the average marginal borrowing rate of the BioPorto Group, 6.0%.

In applying IFRS 16 for the first time, the group has used the following practical methods permitted by the standard:

- the use of a single discount rate to a portfolio of leases with reasonably similar characteristics, and
- the exclusion of initial direct costs for the measurement of the right-of-use asset at the date of initial application.

Updated accounting policy for leases

The group leases office space and vehicles. Until 2018, leases were classified as operating leases. Payments made under operating leases were charged to profit or loss on a straight-line basis over the period of the lease.

From January 1, 2019, leases, except for short term assets in which the lease term is 12 months or less, or low value assets, are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the group.

Right-of-use assets are initially measured at the amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments. Lease liabilities are initially measured as the net present value of the future lease payments discounted by the incremental borrowing rate.

The right-of-use asset is depreciated over the shorter of the asset's useful life or the lease term on a straight-line basis.

Each lease payment is allocated between the liability and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

Lease costs are not split into service components and rental costs but are accounted for as a single lease component. Variable service components invoiced separately are expensed as operational costs.

The implementation has had the following impact on the balance sheet for the numbers of the BioPorto Group:

	Group DKK thousand
Rental and operating lease commitments at 31 December 2018	5,225
Discounting (6%)	(478)
Lease liability recognized in statement of financial position on 1 January 2019	**4,747**

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

Management's priorities for 2019 are:

- Submit FDA application for The NGAL Test in children
- Submit renewed FDA application for The NGAL Test in adults with additional required data
- Increase RUO sales in the U.S.
- Expand the U.S. organization to preparefor launch of The NGAL Test
- Review new opportunities for NGAL and the antibody library
- Grow total revenues by 23%

Revised guidance for 2019

Based on the postponement of the anticipated FDA clearance of the pediatric indication for The NGAL Test, BioPorto has revised its expected revenue in the financial year 2019 from approximately DKK 40 million to approximately DKK 32 million. The revised revenue expectation corresponds to a growth rate of 23% over 2018.

The operating loss (EBIT) in the same period has been revised from a loss of approximately DKK 45 million to a loss of approximately DKK 65 million. The EBIT is primarily impacted by the reduced revenue, investment in the U.S. organization and extra costs for the pediatric clearance of NGAL due to the reported delay.

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
Ole Larsen, CFO
Tel: +45 4529 0000
E-mail: investor@bioporto.com

About BioPorto

BioPorto is an in-vitro diagnostics company that provides diagnostic tests and antibodies to clinicians and researchers around the world. We use our antibody and assay expertise to transform novel research tools into clinically actionable biomarkers that can make a difference in patients' lives. BioPorto is headquartered in Copenhagen, Denmark and is listed on the Nasdaq Copenhagen stock exchange (CPH:BIOPOR).

Statement by the management

The Board of Directors and Executive Management today considered and approved the interim report of the BioPorto Group for the period January 1, 2019 – June 30, 2019.

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 June 30, 2019, and of the results of the Group’s operations and cash flows for the period January 1, 2019 – June 30, 2019.

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, August 15, 2019

Executive Management:

_____

Peter Mørch Eriksen
CEO

Board of Directors:

_____

Thomas Magnussen
Chairman

_____

Torben A. Nielsen
Vice chairman

_____

Kirsten Drejer

Statement of comprehensive income

Income statement

	2019 2nd quarter DKK thousand	2018 2nd quarter DKK thousand	2019 6 months DKK thousand	2018 6 months DKK thousand	2018 12 months DKK thousand
Revenue (Note 1)	7,834	7,137	13,348	11,750	26,016
Production costs	(2,640)	(2,150)	(4,855)	(3,554)	(8,181)
Gross profit/loss	**5,194**	**4,987**	**8,493**	**8,196**	**17,835**
Sales and marketing costs	(9,267)	(5,208)	(16,572)	(10,225)	(20,935)
Research and development costs	(5,421)	(5,914)	(9,601)	(11,879)	(18,676)
Administrative costs	(7,033)	(3,826)	(15,993)	(8,606)	(20,005)
Profit/loss before financial items (EBIT)	**(16,527)**	**(9,961)**	**(33,673)**	**(22,514)**	**(41,781)**
Financial Nets	(235)	105	(251)	154	164
Profit/loss before tax	**(16,762)**	**(9,856)**	**(33,924)**	**(22,360)**	**(41,617)**
Total income taxes	1,009	1,301	1,689	2,583	3,569
Profit/loss for the period	**(15,753)**	**(8,555)**	**(32,235)**	**(19,777)**	**(38,048)**
	DKK	DKK	DKK	DKK	DKK
Profit/loss / comprehensive income per share (EPS & DEPS)	(0.10)	(0.06)	(0.19)	(0.14)	0.23

Statement of comprehensive income

	2019 2nd quarter DKK thousand	2018 2nd quarter DKK thousand	2019 6 months DKK thousand	2018 6 months DKK thousand	2018 12 months DKK thousand
Profit/loss for the period	**(15,753)**	**(8,555)**	**(32,235)**	**(19,777)**	**(38,048)**
Amounts which will be re-classified to the income statement:					
Exchange rate adjustment foreign subsidiaries	(285)	(60)	45	(92)	(277)
Comprehensive income	**(16,038)**	**(8,615)**	**(32,190)**	**(19,869)**	**(38,325)**

Balance sheet

Assets

	2019 30 June DKK thousand	2018 30 June DKK thousand	2018 31 December DKK thousand
Non-current assets			
Intangible assets, property, plant and equipment and right-of-use assets			
Rights and software	1,670	1,476	1,374
Fixtures and fittings, tools and equipment	1,296	688	1,437
Right-of-use assets	3,955	-	-
Total intangible assets, property, plant and equipment and right-of-use assets	**6,921**	**2,164**	**2,811**
Financial assets			
Deposits	774	752	752
Total financial assets	**774**	**752**	**752**
Total non-current assets	**7,695**	**2,916**	**3,563**
Current assets			
Inventories	3,737	3,859	3,631
Trade receivables	7,152	7,307	8,036
Income tax receivables	5,386	7,437	3,656
Other receivables	1,059	1,403	606
Total inventories and receivables	**17,334**	**20,006**	**15,929**
Cash	51,382	22,529	46,709
Total current assets	**68,716**	**42,535**	**62,638**
Total assets	**76,411**	**45,451**	**66,201**

Balance sheet

Liabilities

	2019 30 June DKK thousand	2018 30 June DKK thousand	2018 31 December DKK thousand
Equity			
Share capital	174,944	155,510	165,688
Exchange-rate adjustments	(302)	(162)	(347)
Retained earnings	(113,377)	(118,257)	(109,144)
Total equity	**61,265**	**37,091**	**56,197**
Liabilities			
Non-current liabilities			
Lease obligation	1,193	-	-
Other non-current liabilities	622	725	787
Total non-current liabilities	**1,815**	**725**	**787**
Current liabilities			
Current portion of non-current liabilities	2,796	157	141
Trade payables	2,420	3,911	4,451
Other payables	8,115	3,567	4,625
Total current liabilities	**13,331**	**7,635**	**9,217**
Total liabilities	**15,146**	**8,360**	**10,004**
Total equity and liabilities	**76,411**	**45,451**	**66,201**

Statement of changes in equity

	Share capital DKK thousand	Share premium DKK thousand	Exchange-rate adjustments DKK thousand	Retained earnings DKK thousand	Total DKK thousand
Equity at 1 January 2019	165,688	-	(347)	(109,144)	**56,197**
Comprehensive income					
Profit/loss for the year / Comprehensive income	-	-	-	(32,235)	**(32,235)**
Adjustment of foreign currency fluctuations on subsidiaries	-	-	45	-	**45**
Transactions with owners					
Issue	9,256	27,493	-	-	**36,749**
Issue cost	-	(736)	-	-	**(736)**
Share-based compensation	-	-	-	1,245	**1,245**
Transferred to Retained earnings	-	(26,757)	-	26,757	**-**
Equity at 30 June 2019	**174,944**	**-**	**(302)**	**(113,377)**	**61,265**

	Share capital DKK thousand	Share premium DKK thou-sand	Exchange-rate adjustments DKK thousand	Retained earnings DKK thousand	Total DKK thousand
Equity at 1 January 2018	155,510	-	(70)	(99,372)	**56,068**
Comprehensive income					
Profit/loss for the year/ comprehensive income	-	-	-	(19,777)	**(19,777)**
Adjustment of foreign currency fluctuations on subsidiaries	-	-	(92)	-	**(92)**
Transactions with owners					
Share-based compensation	-	-	-	892	**892**
Equity at 30 June 2018	**155,510**	**-**	**(162)**	**(118,257)**	**37,091**

Cash flow statement

	2019 6 months DKK thousand	2018 6 months DKK thousand	2018 12 months DKK thousand
Profit/loss before financial items	(33,673)	(22,514)	(41,781)
Amortization, depreciation and impairment losses	1,445	268	543
Warrants	1,245	892	(865)
Cash generated from operations before working capital	**(30,983)**	**(21,354)**	**(42,103)**
Changes in working capital	1,711	(2,525)	(631)
Cash generated from operations	**(29,272)**	**(23,879)**	**(42,734)**
Financials, net	(229)	25	(74)
Tax refund	-	-	4,799
Cash flows from operating activities	**(29,501)**	**(23,854)**	**(38,009)**
Investments in rights and software	(425)	-	(52)
Investments in operating equipment	(29)	(539)	(1,410)
Investments in financial assets	(22)	-	(21)
Cash flows from investing activities	**(476)**	**(539)**	**(1,483)**
Issue, gross proceeds	36,749	-	40,000
Issue cost	(736)	-	(681)
Reduction of non-current liabilities	(164)	(158)	(158)
Reduction of lease obligation	(1,199)	-	(40)
Cash flows from financing activities	**34,650**	**(158)**	**39,121**
Net cash flow from operating, investing and financing activities	**4,673**	**(24,551)**	**(371)**
Cash and cash equivalents at beginning of period	46,709	47,080	47,080
Cash and cash equivalents end of period	**51,382**	**22,529**	**46,709**

Note 1

Segment reporting

Geographic distribution	2019 2nd quarter DKK thousand	2018 2nd quarter DKK thousand	2019 6 months DKK thousand	2018 6 months DKK thousand	2018 12 months DKK thousand
Europe	2,136	2,904	4,209	5,142	11,005
North America	4,014	3,083	6,862	4,890	12,161
Asia	1,553	983	2,128	1,406	2,445
Other countries	131	167	149	312	405
Revenue	**7,834**	**7,137**	**13,348**	**11,750**	**26,016**

Product groups	2019 2nd quarter DKK thousand	2018 2nd quarter DKK thousand	2019 6 months DKK thousand	2018 6 months DKK thousand	2018 12 months DKK thousand
NGAL revenue					
Product sales	2,657	2,816	3,921	3,693	9,195
Other NGAL revenue	1,168	455	1,168	455	1,440
Total NGAL revenue	3,825	3,271	5,089	4,148	10,635
Other products and license revenue					
ELISA kits	1,415	1,570	2,463	2,962	4,825
Antibodies	2,354	2,176	5,330	4,323	9,369
Royalty	31	18	97	57	41
Other products and licenses	209	102	369	260	1,146
Total other products and license revenue	4,009	3,866	8,259	7,602	15,381
Revenue	**7,834**	**7,137**	**13,348**	**11,750**	**26,016**