Interim Report

First nine months of 2017, BioPorto Group

November 7, 2017
Announcement no. 17

BioPorto®

BioPorto A/S CVR DK-17500317

Highlights

60% of patients enrolled for US clinical study by end of October

BioPorto is currently conducting a clinical study to get The NGAL Test™ for diagnosis of Acute Kidney Injury (AKI) approved in the USA.

Since commencement of the clinical study in April 2017, BioPorto has enrolled more than 60% of the 530 patients that will make up the total number of patients in the study and generate the data for BioPorto's US registration application for The NGAL Test™.

BioPorto is on schedule for establishing the data for its US registration application for The NGAL Test™.

BioPorto expects to conclude the enrolment of patients late-2017 or early-2018, and submit its registration application to the FDA in Q1 2018.

Momentum in revenue growth sustained in third quarter 2017

The strong sales momentum, which BioPorto exhibited in the first half of 2017, continued into the third quarter of the financial year where total revenue was DKK 6.0 million – an increase of 30 % compared to same quarter last year. This brought total revenue for the first nine months of 2017 to DKK 18.3 million corresponding to a year-over-year growth rate of 27%.

As previously indicated this year, the primary drivers of growth in the third quarter were a strong performance in sales of The NGAL Test™, which doubled to DKK 0.9 million, and a solid sales performance in antibodies leading to an increase in revenue from DKK 2.1 million last year to DKK 3.3 million this year.

Year-to-date, sales of The NGAL Test™ has increased from DKK 2.3 million to DKK 4.2 million, a very solid growth of 84%, largely attributable to the introduction of Research Use Only sales in the US causing revenue to increase by 388% year-over-year in the period. Revenue from The NGAL Test™ in the EU and the rest of the world has also been performing well with a growth rate of 33% in the first nine months of 2017 compared to the same period in 2016.

BioPorto's operating loss before interest and tax (EBIT) for the first nine months of 2017 was DKK 28.3 million compared to a loss of DKK 20.3 million last year in the same period. The increase in the loss is primarily related to higher spending on the US clinical study and increased spending on the US subsidiary.

Successful private placement with proceeds of DKK 41.7 million to prepare for US roll-out

To support the ongoing uptrend in sales, prepare for a commercial US roll-out after FDA approval and strengthen the company's overall liquidity, BioPorto initiated a private placement cash issue on October 27, 2017. In an oversubscribed offering, 13,015,625 new shares corresponding to 9.13 % of the registered shares prior to the implementation of the issue were offered at a price of DKK 3.20 per share to a limited number of selected investors.

The private placement yielded gross proceeds of DKK 41.7 million which has been added to BioPorto's cash position.

Sales and EBIT guidance for 2017 maintained

Revenue in 2017 is expected to be in the range DKK 26-28 million, equivalent to a growth rate of 25-35%.

EBIT forecast for the financial year 2017 is maintained at a loss between DKK 28 - 35 million.

Peter M. Eriksen, CEO comments: "With yet another quarter of high growth, BioPorto continues along the strong execution path we set out on earlier this year. US sales of The NGAL Test™ in the first nine months of 2017 has almost quadrupled compared to last year and ROW sales are up 33 %. And our antibody-business also continues to exhibit strong momentum with a hike of 31% from last year to this year. Meanwhile, we have enrolled more than 60% of the patients for our clinical study in the US, which means that we are on-track for handing in our FDA-application for The NGAL Test™ next year. With an oversubscribed private placement of shares in October this year and net proceeds of DKK 41.0 million, BioPorto is in excellent shape to prepare and execute an optimal commercial US roll-out of The NGAL Test™ once FDA approval has been obtained."

Investor meeting

In connection with the release of the interim report for the first nine months of 2017, BioPorto will host an investor meeting on November 7, 2017 at 3 pm. The meeting will be held at Tuborg Havnevej 15 st., 2900 Hellerup, Denmark. To attend the meeting, please sign up at investor@bioporto.com.

Financial highlights

	2017 3rd quarter DKK thousand	2016 3rd qarter DKK thousand	2017 9 months DKK thousand	2016 9 months DKK thousand	2016 12 months DKK thousand
Revenue	5,980	4,606	18,343	14,442	20,720
Operating profit/loss (EBIT)	(10,665)	(7,126)	(28,340)	(20,284)	(25,047)
Net financials	146	(36)	(138)	(139)	148
Operating profit/loss before tax	(10,519)	(7,162)	(28,478)	(20,423)	(24,899)
Profit/loss for the period	(9,081)	(6,662)	(25,278)	(18,825)	(22,800)
Total comprehensive income	(9,133)	(6,667)	(25,433)	(18,782)	(23,113)
Non-current assets	2,696	1,785	2,696	1,785	3,069
Current assets (excl. Cash)	15,988	11,641	15,988	11,641	11,931
Cash	13,281	18,991	13,281	18,991	35,641
Total assets	31,965	32,417	31,965	32,417	50,641
Share capital	142,494	129,599	142,494	129,599	142,494
Equity	21,217	27,153	21,217	27,153	44,291
Non-current liabilities	1,003	46	1,003	46	1,204
Current liabilities	9,745	5,218	9,745	5,218	5,146
Total equity and liabilities	31,965	32,417	31,965	32,417	50,641
Cash flows from operating activities	(6,828)	(5,059)	(22,297)	(15,459)	(19,660)
Cash flows from investing activities, net	(19)	(0)	(57)	(401)	(401)
Of which investment in property, plant and equipment	0	0	(37)	(157)	(157)
Cash flows from financing activities	(1)	(6)	(6)	(16)	20,836
Total cash flows	(6,848)	(5,065)	(22,360)	(15,876)	774
Revenue growth	30%	-2%	27%	-1%	2%
Gross margin	71%	70%	73%	74%	76%
EBIT margin	-178%	-155%	-154%	-140%	-121%
Equity ratio (solvency)	66%	84%	66%	84%	87%
Return on equity	Negative	Negative	Negative	Negativ	Negative
Average number of employees	25	27	26	27	27
Average number of shares (1,000)	142,494	129,599	142,494	129,599	131,025
Earnings per share (EPS), DKK	(0.06)	(0.05)	(0.18)	(0.15)	(0.17)
Net asset value per share, year-end, DKK	0.15	0.21	0.15	0.21	0.31
Share price, period-end, DKK	3.25	1.92	3.25	1.92	2.10

Management review

Majority of patients enrolled in US clinical study for The NGAL Test™

Since commencement of the clinical study for The NGAL Test™ in April 2017 more than 60 % have been enrolled, which means that BioPorto is on schedule for establishing the data for its US registration application for The NGAL Test™.

BioPorto expects to conclude the enrolment of patients late-2017 or early-2018, and submit its registration application to the FDA in Q1 of 2018. Upon receiving expected approval, BioPorto will execute a targeted roll-out strategy, which will be developed and implemented in parallel with the FDA – clearance process period.

Successful private placement with proceeds of DKK 41.7 million to prepare for US roll-out

To support the ongoing uptrend in sales, prepare for a commercial US roll-out after FDA approval and strengthen the company's overall liquidity, BioPorto initiated a private placement cash issue on October 27, 2017. In an oversubscribed offering, 13,015,625 new shares at corresponding to 9.13 % of the registered shares prior to the implementation of the issue were offered at a price of DKK 3.20 per share to a limited number of selected investors. The private placement yielded net proceeds of approximately DKK 41.0 million which has been added to BioPorto's cash position.

Continued support for improving current AKI diagnosis and treatment

Since May 2017, a number of scientific articles have been published with data supporting both BioPorto's The NGAL Test™, and more generally, the combination of NGAL and serum creatinine for the diagnosis of AKI to reduce overall treatment costs.

The scientific proof has stimulated the overall interest in NGAL and the current issues facing the diagnosis and treatment of AKI, not only in the US, but also in other countries.

In October 2017, a group of experts (David Collister et al.) published an article in Clinical Journal of the American Society of Nephrology named "Health Cost Associated with AKI". Based on Canadian population of adults hospitalized in Alberta between 2002 and 2009, they established, that the estimated incremental cost of AKI in Canada is over CAD 200 million per year and conclude, that "…Severity of AKI, need for dialysis, and lack of kidney recovery are associated with significant health care costs in hospitalized patients and persist a year after admission. Strategies to identify, prevent, and facilitate kidney recovery are needed".

Revenue from The NGAL Test™ continues to soar: Sales doubled in third quarter from 2016 to 2017

In the first half of 2017 revenue from The NGAL Test™ increased by 80% compared to the same period in 2016. The impressive growth momentum was sustained in the third quarter 2017, where revenue doubled from DKK 0.45 million in 2016 to DKK 0.9 million in 2017.

In the period from January 2017 to September 2017, sales of The NGAL Test™ increased from DKK 2.3 million to DKK 4.2 million, a very solid growth of 84%.

Growth in the revenue of The NGAL Test™ is still primarily driven by increased Research Use Only sales in the US, resulting from BioPorto's targeted focus on expanding the general knowledge of NGAL as an early biomarker of Acute Kidney Injury. As a result, year-over-year sales in 2017 in the US has increased by 388%.

In the EU and the Rest of the World (ROW) sales of The NGAL Test™ has also increased considerably as BioPorto has internalized sales efforts in several markets where distributors previously did not perform well. In total, sales to the EU and ROW has grown 33% year-to-date compared to the same period in 2016.

New strategy delivers high growth in sales of antibodies

Adding to previous quarters growth, BioPorto's focus on larger bulk orders to assay developers within the antibody product line has continued to expand the business in the third quarter of 2017.

In the quarter, sales increased from DKK 2.1 million last year to DKK 3.3 million this year, corresponding to a growth of 58%. This brought the total revenue from the sale of antibodies in the first nine months of 2017 to DKK 9.4 million – a 31% increase over last years' DKK 7.2 million.

Financial review

Revenue

The strong sales momentum, which BioPorto exhibited in the first half of 2017 continued into the third quarter of the financial year where total revenue was DKK 6.0 million – an increase of 30% compared to same quarter last year. The growth for the quarter was primarily driven by sales of the NGAL Test™ and increase in sales of antibodies.

Total revenue for the first nine months of 2017 amounted to DKK 18.3 million corresponding to a year-over-year growth rate of 27%. Growth in revenue of The NGAL Test™ is still primarily driven by increased Research Use Only sales in the US, resulting from BioPorto's targeted focus on expanding the general knowledge of NGAL as an early biomarker of Acute Kidney Injury. As a result, year-over-year sales in 2017 in the US has increased by 388%.

In the EU and the ROW sales of The NGAL Test™ have also increased considerably as BioPorto has internalized sales efforts in several markets where distributors previously did not perform well. In total, sales to the EU and ROW has grown 33% year-to-date compared to the same period in 2016.

Antibody sales have also been very satisfying for the first 9 months of 2017 and amounted to DKK 9.4 million, which is 31% higher than the same period in 2016. This increase is due to a focused effort with a number of select distributors combined with an increase in bulk orders.

ELISA Animal NGAL kits sales were 27% higher for the first 9 month of 2017 compared to sales in the first 9 months of 2016. ELISA MBL experienced a 8% growth year-over-year and ended at DKK 1.9 million. On the other hand, sales of ELISA Human NGAL kits is 36% lower in the first 9 months in 2017 compared to the first 9 months of 2016. The main reason for the decrease is a shift to turbidimetry platforms. Finally, Other Sales is 19% lower year-to-date compared to 2016.

Figure 1. Revenue by quarter (DKKm)

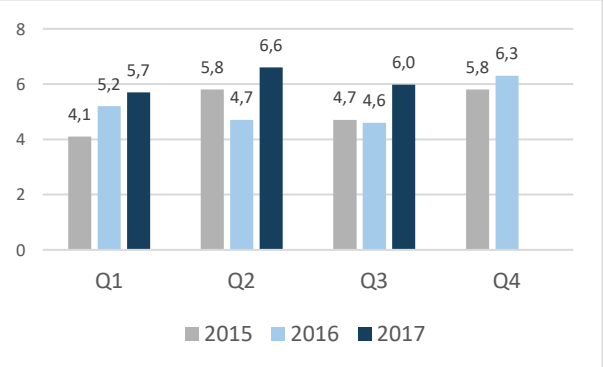
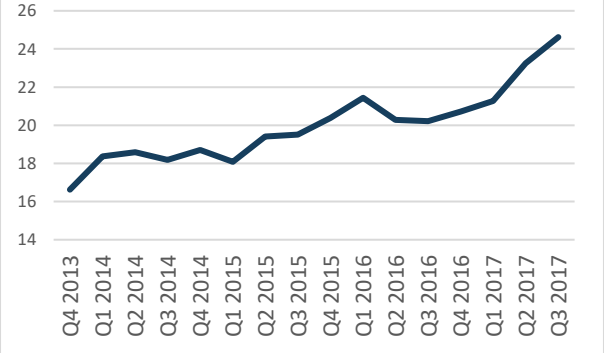


Figure 2. Revenue, LTM (DKKm)



Operating costs and operating results

For the first 9 months of 2017, production costs totalled DKK 5.0 million, bringing the gross profit to DKK 13.3 million and the gross margin to 73%. The gross margin was 74% in same period in 2016 and the decrease is mainly related to bulk orders with lower gross margin, lower license/royalty income and inventory write-down of expired products.

Capacity costs year-to-date amounted to DKK 41.6 million versus DKK 30.9 million last year. Capacity costs have increased predominantly due to the cost associated with the US clinical study and operation costs for the US subsidiary.

In the first nine months of 2017 BioPorto's operating loss before interest and tax (EBIT) amounted to DKK 28.3 million compared to a loss of DKK 20.3 million the previous year. The increased loss is a result of the cost for the US clinical study and running the US organization.

Profit/loss before and after tax

Net financials for the first 9 months in 2017 were DKK -0.1 million, which is on par with 2016. After income recognition of tax of DKK 3,2 million in this period, the net profit for the period amounts to a loss of DKK 25.3 million compared to a loss of DKK 18.8 million for the first nine month of 2016.

Balance sheet

At the end of September 2017, BioPorto's balance sheet totalled DKK 32.0 million. Total non-current assets were DKK 2.7 million, a modest reduction of DKK 0.4 million compared to December 31, 2016.

Inventories and receivables amounted to DKK 16.0 million by the end of September 2017, compared to DKK 11.9 million December 31, 2016. The cash position was DKK 13.3 million as of September 30, 2017.

At the end of September 2017, equity amounted to DKK 21.2 million compared to DKK 44.3 million at the beginning of the year. Liabilities on September 30, 2017 totalled DKK 10.7 million and consisted primarily of trade payables and other debt.

Cash flow statement

Cash flows generated by operating activity were DKK -22.3 million in the first 9 months of 2017 compared to DKK -15.5 million last year. Investments in the period amounted to DKK 0.1 million and cash flows generated by financing activities were DKK 0.0 million. The cash flows for the period thus ended up at DKK -22.4 million compared to DKK -15.9 million in the first 9 months of 2016.

Significant events after the end of the period

To support the ongoing uptrend in sales, prepare for a commercial US roll-out after FDA approval and strengthen the company's overall liquidity, BioPorto initiated a private placement cash issue on October 27, 2017. In an oversubscribed offering, 13,015,625 new shares at corresponding to 9.13 % of the registered shares prior to the implementation of the issue were offered at a price of DKK 3.20 per share to a limited number of selected investors. The private placement yielded net proceeds of approximately DKK 41.0 million which has been added to BioPorto's cash position.

Accounting policies

The interim report is presented in accordance with the accounting policies applied in the Group's annual report for 2016.

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

The management priorities for the remaining part of 2017 comprise of:

- Concluding the patient recruitment for clinical study relating to the FDA registration of The NGAL Test™,
- Increasing the number of Research Use Only sites for The NGAL Test™ in the US
- Increasing non-US sales of The NGAL Test™
- Launching new immunodeficiency products

Guidance for 2017 maintained

Based on the performance and momentum for the first nine months of 2017, the management of BioPorto reiterates its latest guidance for the financial development in 2017. Hence, full year revenue is expected in the range of DKK 26-28 million, equivalent to a growth rate of 25–35%. The growth will primarily be the result of increased revenues from The NGAL Test™ and the antibody portfolio through targeted sales efforts.

EBIT for the financial year 2017 is forecasted to be a loss of DKK 28 - 35 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:

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About BioPorto
BioPorto Diagnostics A/S is an in-vitro diagnostics company that provides healthcare professionals in clinical and research settings with a range of diagnostic tests and antibodies. Our pioneering product portfolio includes assays for underdiagnosed diseases, including our NGAL tests for acute kidney injury. BioPorto is headquartered in Copenhagen, Denmark and is listed on the Nasdaq Copenhagen stock exchange.

Statement by the management

The Board of Directors and the Management Board today considered and approved the interim report of the BioPorto Group for the period January 1, 2017 – September 30, 2017.

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, 2017, and of the results of the Group’s operations and cash flows for the period January 1, 2017 – September 30, 2017.

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, November 7, 2017

Management board:

_____
Peter Mørch Eriksen
CEO

Board of Directors:

_____
Thomas Magnussen
Chairman

_____
Torben A. Nielsen
Vice chairman

_____
Kirsten Drejer

_____
Niels Christian Nielsen

Statement of comprehensive income (condensed)

Income statement

	2017 3rd quarter DKK thousand	2016 3rd qarter DKK thousand	2017 9 months DKK thousand	2016 9 months DKK thousand	2016 12 months DKK thousand
Revenue (Note 1)	5,980	4,606	18,343	14,442	20,720
Gross profit/loss	**4,237**	3,203	**13,302**	10,639	15,693
Profit/loss before financial items (EBIT)	**(10,665)**	**(7,126)**	**(28,340)**	**(20,284)**	**(25,047)**
Profit/loss before tax	**(10,519)**	**(7,162)**	**(28,478)**	**(20,423)**	**(24,899)**
Profit/loss for the period	**(9,081)**	**(6,662)**	**(25,278)**	**(18,825)**	**(22,800)**
	DKK	DKK	DKK	DKK	DKK
Profit/loss / comprehensive income per share (EPS & DEPS)	(0.06)	(0.05)	(0.18)	(0.15)	(0.17)

Statement of comprehensive income

	2017 3rd quarter DKK thousand	2016 3rd qarter DKK thousand	2017 9 months DKK thousand	2016 9 months DKK thousand	2016 12 months DKK thousand
Profit/loss for the period	**(9,081)**	**(6,662)**	**(25,278)**	**(18,825)**	**(22,800)**
Amounts which will be re-classified to the income statement:					
Exchange rate adjustment foreign subsidiaries	(52)	(5)	(155)	43	(313)
Comprehensive income	**(9,133)**	**(6,667)**	**(25,433)**	**(18,782)**	**(23,113)**
	DKK	DKK	DKK	DKK	DKK
Profit/loss / comprehensive income per share (EPS & DEPS)	(0.06)	(0.05)	(0.18)	(0.14)	(0.18)

Balance sheet

ASSETS	2017 30 September DKK thousand	2016 30 September DKK thousand	2016 31 December DKK thousand
Non-current assets			
Property, plant and equipment and intangible assets			
Fixtures and fittings, tools and equipment	303	453	400
Rights and software	1,662	622	1,959
Total financial assets	731	710	710
Total non-current assets	**2,696**	**1,785**	**3,069**
Current assets			
Total inventories and receivables	15,988	11,641	11,931
Cash	13,281	18,991	35,641
Total current assets	**29,269**	**30,632**	**47,572**
TOTAL ASSETS	**31,965**	**32,417**	**50,641**

Balance sheet

LIABILITIES	2017 30 September DKK thousand	2016 30 September DKK thousand	2016 31 December DKK thousand
Equity			
Share capital	142,494	129,599	142,494
Treasury shares	0	0	0
Exchange-rate adjustments	(468)	43	(313)
Retained earnings	(120,809)	(102,489)	(97,890)
Total equity	**21,217**	**27,153**	**44,291**
Liabilities			
Non-current liabilities			
Lease obligation	0	46	40
Other non-current liabilities	1,003	0	1,164
Non-current liabilities	**1,003**	**46**	**1,204**
Current liabilities			
Current portion of non-current liabilities	208	24	242
Trade payables	3,817	1,103	1,169
Other payables	5,720	4,091	3,735
Current liabilities	**9,745**	**5,218**	**5,146**
Total liabilities	**10,748**	**5,264**	**6,350**
TOTAL LIABILITIES	**31,965**	**32,417**	**50,641**

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 1 January 2017	142,494	0	(313)	(97,890)	**44,291**
Profit/loss for the year / Comprehensive income	0	0	0	(25,278)	**(25,278)**
Other changes in equity	0	0	(155)	2,359	**2,204**
Transferred to Retained earnings	0	0	0	0	**0**
Equity at 30 September 2017	**142,494**	**0**	**(468)**	**(120,809)**	**21,217**

	Share capital DKK thousand	Share premium DKK thousand	Exchange-rate adjustments DKK thousand	Retained earnings DKK thousand	Total DKK thousand
Equity 1 January 2016	129,599	0	0	(85,114)	**44,485**
Profit/loss for the year/ comprehensive income	0	0	0	(18,825)	**(18,825)**
Other changes in equity	0	0	43	1,450	**1,493**
Transferred to Retained earnings	0	0	0	0	**0**
Equity at 30 September 2016	**129,599**	**0**	**43**	**(102,489)**	**27,153**

Cash flow statement

	2017 9 months DKK thousand	2016 9 months DKK thousand	2016 12 months DKK thousand
Profit/loss before financial items	(28,340)	(20,284)	(25,047)
Amortisation, depreciation and impairment losses	431	292	390
Warrants	2,359	1,565	2,061
Cash generated from operations before working capital	**(25,550)**	**(18,427)**	**(22,596)**
Changes in working capital	3,908	3,179	839
Cash generated from operations	**(21,642)**	**(15,248)**	**(21,757)**
Financials, net	(592)	(96)	(124)
Establishment cost, subsidiaries	0	(115)	(115)
Tax (refund)	(63)	0	2,336
Cash flows from operating activities	**(22,297)**	**(15,459)**	**(19,660)**
Purchase of operating equipment	(37)	(157)	(157)
Purchase of rights and software	0	(200)	(200)
Purchase of financial assets	(20)	(44)	(44)
Sale of operating equipment	0	0	0
Cash flows from investing activities	**(57)**	**(401)**	**(401)**
Capital increases	0	0	20,858
Reduction of lease obligation	(6)	(16)	(22)
Cash flows from financing activities	**(6)**	**(16)**	**20,836**
Net cash flow from operating, investing and financing activities	**(22,360)**	**(15,876)**	**774**
Cash and cash equivalents at beginning of period	35,641	34,867	34,867
Cash and cash equivalents end of period	**13,281**	**18,991**	**35,641**

Segments

GEOGRAPHIC DISTRIBUTION:	2017 3rd quarter DKK thousand	2016 3rd qarter DKK thousand	2017 9 months DKK thousand	2016 9 months DKK thousand	2016 12 months DKK thousand
Denmark	395	386	1,045	1,254	1,898
Rest of Europe	2,407	1,982	6,192	5,821	8,182
North America	2,513	1,718	8,330	5,445	7,760
Asia	521	465	2,563	1,640	2,656
Other countries	144	55	213	282	224
Revenue	**5,980**	**4,606**	**18,343**	**14,442**	**20,720**

PRODUCT GROUPS	2017 3rd quarter DKK thousand	2016 3rd qarter DKK thousand	2017 9 months DKK thousand	2016 9 months DKK thousand	2016 12 months DKK thousand
The NGAL test	913	454	4,197	2,280	4,014
ELISA Human NGAL kits	365	557	877	1,378	1,720
ELISA Animal NGAL kits	393	426	1,287	1,012	1,302
ELISA MBL kits	609	784	1,927	1,791	2,347
Antibodies*	3,337	2,114	9,397	7,165	10,192
Other products and licenses	362	271	657	816	1,145
Revenue	**5,980**	**4,606**	**18,343**	**14,442**	**20,720**

* In Q1-Q3 2017, public innovation assistance of DKK 630 thousand relating to the development and production of a new antibody is included as revenue (Q1-Q3 2016: DKK 849 thousand and Q1-Q4 2016: DKK 1.334 DKK thousand).