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BioPorto's 3Q revenue increases 24% year-over-year

BioPorto A/S (CPH:BIOPOR) on Thursday reported that third-quarter revenue increased 24% year-over-year.

In a statement, the Danish biotech company said revenue came in at DKK 6.6 million (US$980,000), compared to DKK 5.4 million (US$800,000) in the prior-year quarter.

BioPorto noted that revenue stemming from its flagship NGAL test for the risk assessment of acute kidney injury (AKI) in patients rose 29% in the quarter year-over-year.

READ: BioPorto to provide additional patient data to back FDA application for NGAL test

The company attributed this increase to the growing interest in the potential uses for NGAL in Research Use Only (RUO) assay. Secondly, the company also said sales of its antibodies were positively affected by higher bulk orders.

BioPorto's release of its 3Q financial results comes as the company seeks US regulatory clearance of the NGAL test for use in children.

Following recent dialog with the US Food and Drug Administration, BioPorto on November 18 announced that it has decided to supplement its pediatric 510(k) application with additional data in order to fully respond to the most recent review shared by the agency.

The valuable study from which BioPorto drew its original dataset demonstrated that the NGAL biomarker can be successfully deployed to assess risk of pediatric acute kidney injury in the critical care setting. However, the FDA disagreed with the clinical community, expressing concern over risk of clinician bias in the data.

BioPorto will provide a follow-on dataset designed to demonstrate NGAL's utility not only to clinicians but also to the FDA. BioPorto expects to submit a revised and supplemented application in the second quarter of 2020.

As a result of the company's decision to provide additional information to the FDA, BioPorto has changed its financial guidance for 2019 to about DKK 29 million (US$4.3 million) in revenue from DKK 32 (US$4.7 million).

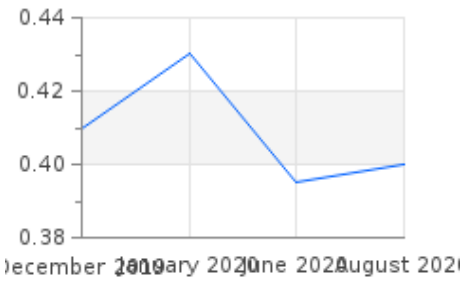
"On top of a good third quarter with satisfying growth in revenue and executing according to plan, we unfortunately had to announce a delay in our US pediatric application process for The NGAL Test," said CEO Peter Eriksen.

"FDA saw some risk of bias in the data from the AWARE study, which we used in our application, which we must address. While this is of course disappointing in the short term, I believe the dialogue and feedback from FDA, along with the additional data we will collect, will strengthen our future commercial position and augment our ongoing adult studies."

Price: 0.4

Market Cap: $79.97 m

1 Year Share Price Graph



Share Information

Code:		THOXF
Listing:		PINK
52 week	**High**	**Low**
	0.4321	**0.3949**
Sector:		**Pharma & Biotech**
Website:		**www.bioporto.com**

Company Synopsis:

BioPorto Diagnostics A/S is an in-vitro diagnostics company that provides healthcare professionals in clinical and research settings a range of diagnostic tests and antibodies. Our pioneering product portfolio includes assays for underserved disease states such as NGAL for acute kidney injury. We sell our products in more than 80 countries through diverse sales channels and partners.

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In the meantime, the company said knowledge and awareness of NGAL as an early biomarker for AKI risk in critically ill patients is growing among nephrologists and physicians as more and more papers describing NGAL's clinical applications are being published in medical journals.

During the world's premier nephrology meeting, called Kidney Week, arranged by the American Society of Nephrology in November in Washington, D.C., BioPorto said AKI and NGAL were highlighted with two oral presentations, 16 posters and abstracts and many discussions with thought leaders.

According to the company, the NGAL Test can detect AKI earlier and more reliably than other tests on the market. AKI is common following kidney transplants and heart-bypass surgery.

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