UK: +44 (0)207 989 0813
NA: +1 646 896 3065
AU +61 2 9280 0700
action@proactiveinvestors.com

06:00 06 May 2019

BioPorto places focus on flagship NGAL kidney-injury test

- The Danish company is aggressively marketing its proprietary NGAL Test, which provides early risk assessment of acute kidney injury (AKI)
- NGAL Test has not yet been approved for use in the US; the FDA wants more data
- Expects FDA clearance of the test for children in the first half of 2019
- Company continues to build up its US sales team

What the company does
BioPorto A/S (CPH:BIOPOR) is an in-vitro diagnostic company based in Hellerup, Denmark that provides a range of diagnostic tests and antibodies to treat obesity and diabetes, innate immunity, allergy and infectious diseases to health care professionals in 80 countries.

The company, which was founded in 2000 and has 28 employees, has been aggressively marketing its proprietary NGAL Test, which provides early risk assessment of acute kidney injury (AKI). BioPorto says its NGAL Test can detect AKI earlier and more reliably than other tests on the market.

AKI is a well-known complication resulting from injury to the kidney, which is common after surgeries such as kidney transplants and heart-bypass surgery.

The NGAL Test helps doctors to tailor a care plan more quickly and effectively than standard testing, which reduces the risk of renal failure and/or death. The test measures NGAL levels, a biomarker which increases in response to injury, as much as 24 hours before it would otherwise be detectable. The company says the standard testing regime can take up 72 hours to detect injury to the kidney.

Share Information

Code:	BIOPOR
Listing:	NASDAQ OMX
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.

action@proactiveinvestors.com

BioPorto already has an established business selling antibodies globally. The company offers more than 400 monoclonal antibodies, which arer types of lab-created proteins that can bind to substances in the body, including cancer cells. The antibodies are made by identical immune cells that all clones of a unique parent cell. The antibodies are used in research disciplines such as microbiology, immune deficiency, renal, peptide hormones and plasma proteins.

Inflection Points
A challenge facing the company is the fact that the NGAL Test has not yet been approved for use in the US, although BioPorto has been pushing for US Food and Drug Administration clearance. In July 2018, the company applied to the FDA to approve the test for adults based on a study of more than 500 patients. But the FDA requested more data to continue the clearance process. As a result, the company has launched a second study of 150 to 200 patients to gather more data to add to its revised FDA application.

Meanwhile, the company last month named Amy Winslow as president of its US subsidiary as it prepares to make a second try with the FDA. Winslow was president and CEO of Magellan Diagnostics, a point-of-care company in Boston.

CEO Peter Eriksen, in the company's 2018 annual report, acknowledged the FDA setback but said the company was lobbying hard both the US medical industry and politicians for approval. He also noted the company last year saw an

80% increase in Research Use Only sales of the NGAL test in the US.

"This is the first step in BioPorto's strategy of expanding the product portfolio vertically to penetrate and capitalize on a massive global market opportunity for the proprietary and leading NGAL technology," the company noted in the report.

BioPorto has entered into agreements with Roche Diagnostics and Siemens Healthcare to help with the distribution of NGAL Test following FDA clearance.

In addition, the EU last year granted BioPorto a patent covering the monitoring of the onset of a renal disorder by NGAL. The NGAL Test is available for diagnostic use in Europe.

U.S. regulatory application for The NGAL Test™

	Adults	Children
Indication	Risk use with AKI	Risk use with AKI
Based on measurements in	Plasma	Urine
Clinical study	Enrolment of up to 200 patients with AKI from 3-5 sites in the US	Retrospective study based on existing U.S. data
Key dates	Expected clearance in 2H 2019	Application expected to be submitted in 1H 2019
Estimated study and application costs in 2019	Approx. DKK 3.5 million	Approx. DKK 2.5 million

Outlook

BioPorto plans to submit two regulatory clearance applications for the NGAL test to the FDA in 2019, one in the first half of the year for clinical use in children under 21 and one in the second half of the year for use in adults. Winslow's efforts will be key as the company builds out its US sales team.

"As we prepare for FDA clearance for The NGAL test, it is critical to establish a strong presence in the US to deliver rapid growth. Amy will lead the charge," said Eriksen.

The company hopes to see some rapid growth in 2019 and beyond. BioPorto reported slightly higher revenue for 2018 versus the prior year. For 2019, the company expects the FDA to approve the NGAL test for children.

Contact the author: patrick@proactiveinvestors.com

Follow him on Twitter @PatrickMGraham

Proactive Investors facilitate the largest global investor network across 4 continents in 4 languages. With a team of analysts journalists & professional investors Proactive produce independent coverage on 1000's of companies across every sector for private investors, private client brokers, fund managers and international investor communities.

Contact us +44 (0)207 989 0813 action@proactiveinvestors.com

No investment advice