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BioPorto focused on flagship NGAL acute kidney-injury test but also looking at coronavirus test

- Proprietary NGAL Test provides early risk assessment of acute kidney injury (AKI)
- Test available for diagnostic use in Europe and Canada but not in the US yet
- Expects 2020 revenue of US$4.3 million based on NGAL sales for research-use-only
- Moving ahead with its Danish partner on co-development of a rapid test to detect coronavirus

What BioPorto does:

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

The Copenhagen-listed company, founded in 2000, has been aggressively marketing its proprietary NGAL Test, which provides an early risk assessment of acute kidney injury (AKI), a well-known complication that is common after surgeries such as kidney transplants and heart-bypass.

BioPorto says its NGAL Test can detect AKI in critically ill patients as quickly as 2 hours. It is the only AKI biomarker that can be measured in both human urine and plasma and can run on standard chemistry analyzers.

The NGAL Test helps doctors 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. The company says rival tests can take up to 72 hours to detect injury to the kidney.

Aside from the test, BioPorto has an established business selling antibodies globally. The company offers more than 400 monoclonal antibodies, which are 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 are all clones of a unique parent cell. The antibodies are used in research disciplines.

How is it doing:

BioPorto's NGAL Test has not yet been approved for diagnostic use in the US, unlike in the EU, Canada, Korea, and Israel. In the US, the test is only available for research-use-only (RUO).

BioPorto has been pushing for US Food and Drug Administration clearance for diagnostic use in children. The company is currently conducting studies for such use in adults. BioPorto will team with Roche Diagnostics and Siemens Healthcare to distributes the test following an anticipated FDA approval.

Following discussion with the FDA, BioPorto announced in November 2019 that it will supplement its pediatric 510(k) application with additional data to fully respond to the most recent review shared by the agency.

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.

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The study from which BioPorto drew its original dataset demonstrated that the NGAL biomarker can be successfully deployed to assess the risk of pediatric AKI, winning it a sought-after Breakthrough designation. The company says this was the first pediatric IVD Breakthrough designation awarded by the FDA in years.

But the FDA disagreed with the clinical community, expressing concern over a risk of clinician bias in the data.

BioPorto is providing a follow-on dataset study designed to demonstrate NGAL's utility for pediatrics not only to clinicians but also to the FDA. The company expects to submit a revised application in the second quarter of 2020.

It has recruited 10 leading US pediatric hospital sites to participate in the study and held a pre-submission meeting with the FDA. Once the agency certifies the test, BioPorto will team with Roche Diagnostics and Siemens Healthcare to help with the distribution.

During the current year, the company will also work to secure data to support a bolstered application for FDA clearance of the NGAL Test in adults. It also will begin to review new opportunities for NGAL and the antibody library to define a pipeline of future targeted assays and biomarkers.

To strengthen its financial position, support the execution of its strategy and build awareness for the NGAL Test, BioPorto in March launched a rights issue that raised US$5.6 million.

In the first quarter of 2020, which ended on March 31, Bioporto saw its revenue jump 67% year-over-year thanks to demand for the NGAL test.

It said it expects full-year 2020 revenue to be US$4.3 million based on "double-digit growth" in NGAL sales for RUO across regions, while sales of antibodies and ELISA kits for pharmaceutical research and in-vitro diagnostic testing are expected to decline due to the group's narrower focus on its own antibody library.

The company noted that its guidance does not include any sales of FDA-cleared NGAL tests in the US in 2020.

However, the company has cautioned that the coronavirus (COVID-19) pandemic has already affected its operations, with its pediatric study is on hold and costs related to the clinical trial as well as the submission of the FDA application will be postponed to the second half of 2020.

COVID-19 testing developments

The company is moving ahead with its Danish partner on the co-development of a rapid test to detect the deadly virus.

BioPorto and the University of Southern Denmark (SDU) are working on a test that will leverage the company's patented Generic Rapid Assay Device (gRAD) technology to deliver results in less than 10 minutes. If successful, a test could be available in the second half of the year.

Separately, the company and leading hospitals in the Capital Region of Denmark have started a 12-month randomized pilot study called COMBAT COVID-19 to treat infected patients suffering from Adult Respiratory Distress Syndrome and receiving respiratory therapy with drug Ilopros.

The study, funded with a US$400,000 grant from Innovation Fund Denmark, will compare the efficacy of Iloprost to placebo in a group of 80 patients. The biomarker thrombomodulin, an indicator of capillary damage, will be used to identify and enroll patients with severe capillary injury into the study. BioPorto has developed a thrombomodulin test.

Inflection points:

- Obtain FDA approval of the NGAL Test for pediatrics
- Collect data to support the submission of adult application for the test
- Review new opportunities for NGAL Test and company's antibody library

- Continue to build awareness for NGAL Test, especially in the US
- More news on rapid coronavirus test development

What the boss says:

"Our efforts to increase awareness of NGAL for the diagnosis of AKI were bolstered by the US government's attention on kidney health initiatives," according to BioPorto CEO Peter Eriksen.

"These were catalyzed by a White House executive order to invest in education as well as in therapeutic and preventative measures that will improve the lives of patients with kidney disorders. We expect this focus on the kidney will ultimately support the case for NGAL and the need to address the challenges of AKI."

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