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Announcement no. 4

Comeback with a view to growth.

2016 was a landmark year for BioPorto. From the beginning of the year, we worked intensively to prepare for the launch of The NGAL Test™ in the US. This focus was changed when we, and contrary to expectation, were notified that the FDA had rejected our application. Instead, we allocated our efforts to establishing the prerequisites for a new submission process and adapted our costs to the current level of activity to make us more efficient and agile.

"The potential and importance of a test that can detect acute kidney injury, optimize treatment procedures, reduce mortality rates and save billions of dollars for the healthcare system, is enormous. And we remain convinced that The NGAL Test™ is the test that could realize that potential. We therefore chose, with massive support from leading US clinicians and doctors, to continue our efforts in obtaining an FDA approval of The NGAL Test™ in the US. After positive dialogue with the FDA, we finished the protocol for The NGAL Test™ in January 2017, which shall be the foundation for the new clinical study that will generate data for the new registration application in the US, Peter Mørch Eriksen, CEO in BioPorto says.

In 2016, BioPorto used significant resources on establishing the foundation for the new application process to the FDA, but also managed to sustain new commercial results, e.g. by entering into a global distribution agreement with Siemens Healthcare regarding NGAL.

"In 2016, by bringing our shared ambitions, will and focus together with an enhanced new process knowledge, we have created the framework for a new FDA registration application. Despite tough odds, we strengthened the strategic position of The NGAL Test™ through scientific support, intensification of our IP rights and optimized marketing conditions through a new distribution agreement.

This has prompted an increase in sales of The NGAL Test™, and this trend will continue as we expect a revenue growth of 20-35 % in 2017, driven by research sales in the US and the agreement with Siemens. In 2017, our full attention is directed to these sales initiatives and our targeted efforts to secure a successful approval, that will kick-start sales of The NGAL Test™ in the US in 2018,", Peter Mørch Eriksen remarks.

Further details from:
Peter Mørch Eriksen, CEO
Gry Husby Larsen, General Counsel
Phone 45 29 00 00, mail investor@bioporto.com

The kidney biomarker NGAL
Every year about 13 million people are struck by acute kidney injury worldwide, of whom about 4 million die. Nevertheless, there has been no real progress in methods of diagnosing kidney injury over the last half century. Existing methods, such as serum creatinine determination, only signal kidney failure 24-72 hours after the injury has taken place. In contrast, NGAL rises to diagnostic levels within a few hours of kidney injury and thus enables the physician to make vital clinical decisions before the damage progresses to potentially fatal renal shutdown. In addition to helping the patient, cost-benefit analyses show that implementing NGAL testing will contribute to reducing hospital costs in the management of kidney injury and its consequences.

About BioPorto
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. BioPorto has its headquarters in Copenhagen, Denmark and is listed on the NASDAQ Copenhagen stock exchange.