September 25, 2015
Announcement no. 20

Submission of FDA application for The NGAL Test™

Today, BioPorto has submitted a registration application to the US Food and Drug Administration, FDA, for approval of The NGAL Test™, cf. company announcement no. 13 of July 3, 2015. The submission is based on finalized data from the clinical study in the US that satisfactorily support the application's claim regarding the use of The NGAL Test™ in the diagnosis of acute kidney injury. BioPorto expects to use the data commercially after FDA approval is obtained.

Alongside the application process, BioPorto has initiated the establishment of a business platform in the US. This will include the company's own US sales and support organization in charge of the commercialization of The NGAL Test™ when FDA approval is expectedly achieved in early 2016.

The submission of the FDA application does not alter expectations for BioPorto's revenue and profit in 2015, as most recently expressed in the interim report for the first half of 2015.

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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.