

June 30, 2014
Announcement no. 12

BioPorto maintains its assessment of the IP situation regarding NGAL and continue with the divisional application

On April 1, 2014, the European Patent Office (EPO) decided that BioPorto's NGAL cutoff patent no. EP1831699 did not meet the requirements for adequate description, see announcement no. 8 of April 1, 2014. BioPorto has received the grounds for invalidation, which is available from epoline.org, and has had the opportunity to assess the grounds. Based hereon, BioPorto maintains the assessment that the company still has a very strong patent portfolio in the NGAL area. First, the company has a number of other important patents (NGAL Exclusion, NGAL Ratio, NGAL Trauma and NGAL Forms patents) and second, the company has a divisional European NGAL cutoff patent application pending before the EPO, which covers the same area and has the same priority date as the invalidated patent. The company will seek to improve the shortcomings, which led to the invalidation. The amendments will be filed in September 2014 at the latest.

Peter Mørch Eriksen, CEO of BioPorto, comments: "We need to work with some of the descriptions in the patent, so the skilled person is not in doubt of how the invention is carried out. In our assessment, the divisional application has a good chance of approval with these amendments. "

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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 OMX Copenhagen stock exchange.