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Announcement no. 11

BioPorto pre-launches pioneering kidney injury test

BioPorto is now pre-launching The NGAL Test for kidney injury in its new user-friendly format which can be used on most fully automated clinical chemistry analyzers. In preparation for the pre-launch, BioPorto has focused strongly on optimizing the sales channels for the test and has planned a launch in several steps. For the rest of this year, the test will be tried out in hospitals in strategically important markets across the world. For the definitive launch of the test for diagnostic use, it must be registered with the national regulatory authorities, initially in Europe through CE-marking, which is expected to be completed by early 2011. Once this registration has been carried out, BioPorto will be ready to sell the test in 40 countries. The next step in the launch process will be taken in the second half of 2011, when the test is also expected to be approved by the FDA (Food and Drug Administration) for sale in the USA, a decisive market for consolidating and spreading the use of The NGAL Test.

BioPorto has marketed NGAL tests since 2005, mainly for research purposes, but with the new test format BioPorto will be entering the lucrative market for routine diagnostics, where the potential for NGAL testing is estimated to amount to more than one billion dollars. To meet hospital laboratories' expectations, BioPorto has developed a homogeneous test format with emphasis on making it easy to get a rapid result. The NGAL Test allows the physician to get vital information on the patient's condition within a very short time, and as the test has been designed to be run on analytical apparatus which is already present in the laboratory; hospitals need not invest in new equipment to implement The NGAL Test.

The NGAL Test and acute kidney injury

Acute kidney injury strikes up to 13 million people a year, of which about 4 million die. Despite this, there has been no real progress in means of diagnosing kidney injury over the last half century. The NGAL Test at last provides physicians with the tool they need to diagnose kidney injury much earlier than ever before. Existing methods, for example the measurement of serum creatinine, only indicate kidney failure 24-72 hours after kidney injury has taken place. In contrast, NGAL determination can demonstrate kidney injury within a few hours and thus allow physicians to take measures before the damage progresses to potentially fatal kidney failure. In addition to the benefit to the patient, cost-benefit analyses have shown that implementation of NGAL testing will contribute to the saving of hospital expenditure on the treatment of patients with kidney damage.

Expectations

Financial expectations for 2010 are maintained, as sales of The NGAL Test in the first few months are primarily for validation and therefore subject to considerable discounts. Sales of the new test are expected to constitute a high proportion of the company's earnings from 2011 onwards.

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