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Announcement no. 20

BioPorto adopts new rapid route to widespread commercialization of kidney test

Successful product development means that BioPorto is now focusing on a new type of NGAL test. The test is designed for use in a wide range of the fully automated systems that are already in use for the vast majority of the millions of tests that are performed every day in hospitals all over the world.

Successful operation (proof of concept) of the new NGAL tests has now been documented. This important milestone opens the way for the next development phases and the use of the new test in central hospital laboratories.

The new test is under development in collaboration with one of the world's leading manufacturers of diagnostic test. The collaboration makes it possible for BioPorto not only to ensure rapid test development, but also to put into production a high quality test on the large scale needed to reach a major portion of the market for kidney tests, which will be achieved by supplying the test to the world's principal manufacturers of diagnostic analytical platforms. In this way BioPorto expects to build up a considerable sale of its own products which can be supplemented by the sale of licenses to the use of its central NGAL cutoff patent.

The need for NGAL tests

Using NGAL tests to diagnose acute kidney injury will lead to a marked improvement in the treatment of the affected patients. Today, there is no competing technology for the early diagnosis of acute kidney injury. Existing methods of determining kidney damage, e.g. the commonly used measurement of serum creatinine, only indicate renal failure resulting from a prior kidney injury at a relatively late stage (24-72 hours) after the injury has occurred. In contrast, an NGAL determination will reveal the occurrence of kidney injury within a few hours.

US health statistics show that over 5 million patients per year are admitted to the country's intensive care units, where the NGAL test is expected to win particular acceptance as a routine test. The patients stay on the unit for over 6 days, on average. Transferring these data to the industrialized world as a whole, this would mean a total of 80-90 million days of admission per year, and with an estimated use of 1-4 tests per day, this adds up to a very considerable market potential. BioPorto's new NGAL test has been developed to cover a major portion of this market.

Development and production of the new NGAL test

It has been important for BioPorto to find the right collaborator to develop the new NGAL test for fully automated equipment. In early 2009 a development agreement was signed with one of the foremost companies in this area, which is already supplying the market with tests of the highest quality for other disease markers using the same advanced technology.

After the development phase, production will be established at the capacity to cover the expected demand. As part of its contribution to the collaboration, BioPorto will be responsible for the production of the antibodies and calibrator material which are the essential components of the test, and will also retain ownership of its important IP rights to NGAL. The coming months will see an up-scaling to actual production and the performance of stability studies. If the work progresses according to plan, the test will be ready for launch in the first half of 2011.

Tests for fully automated systems

There are two basic types of test in fully automated systems, homogeneous and heterogeneous. BioPorto's new NGAL test is homogeneous, which in this context means that it consists of a single



analytical step and can readily be adapted to the systems that are supplied by the vast majority of manufacturers of automated analytical platforms. In contrast, a heterogeneous test depends on a separation step to determine the binding of the marker to a surface, which in practice means that a particular test is developed for a particular system and cannot be transferred to another heterogeneous system. For example, Abbott Laboratories have announced that they will be launching a heterogeneous NGAL test in 2009.

The development of BioPorto's new homogeneous NGAL test is aimed at central hospital laboratories and opens up the NGAL market to most of the major suppliers of analytical systems such as Roche, Siemens, Olympus and others. After registration, the NGAL test can be offered as part of the companies' portfolio of specific tests that are available on their equipment. BioPorto wishes to establish supply agreements with all existing suppliers of homogeneous tests for their own fully automated systems, so that this large market sector will be covered as widely as possible. These agreements are expected to be established in the course of 2010. At the same time, adjustment of the test to the individual suppliers' systems will be started and the new test will be registered in the different countries concerned.

BioPorto's existing NGAL tests

BioPorto will continue its endeavor to increase sales of its NGAL ELISA kit, particularly by registering and marketing the test in those countries that today use mainly ELISA tests. BioPorto's activities in China and India have thus been intensified in 2009 and are expected to be further expanded.

Licensing

In negotiations on license access to its NGAL IP rights, BioPorto has hitherto been open to various agreement models. However, the development of the homogeneous test for measuring NGAL in both blood and urine has now progressed to the point where BioPorto expects to be able to cover this part of the NGAL market with its own products, and the Company may therefore choose to reserve its rights by not granting licenses for homogeneous test applications.

However, this does not preclude entering into license agreements covering other areas. BioPorto will continue to be open to such license agreements, which will favor the widespread use and overall recognition of NGAL as a renal marker.

Expectations

The costs of the continued development of the new NGAL test have been included in the budget for 2009 and the financial expectations for the current year are therefore unchanged. Sales of the new test are expected to contribute to earnings from 2011 onwards.

Further details

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About BioPorto A/S

BioPorto develops and markets antibodies and antibody-based products, including tests to diagnose human disease, both for the benefit of individual patients and to promote efficiency in the health sector. The Company's developments include a test (NGAL) to diagnose and monitor acute kidney injury.

BioPorto's strategy is to develop new methods based on its antibody portfolio that can be patented and achieve a wide use in the diagnosis of various diseases.

BioPorto was founded in 2000 and has about 25 employees. The Company's shares are listed on NASDAQ OMX Copenhagen (symbol: BIOPOR). www.bioporto.com