

## **TYRIAN DIAGNOSTICS: ADVANCEMENTS ON MILESTONES FOR 2011**

SYDNEY, Australia 1 July 2011: Over the past 6 months Tyrian Diagnostics Limited (ASX:TDX) has focused on advancing its programme on rapid diagnostics for chronic respiratory disease, partnering its Tuberculosis assets and supporting the on-going development and marketing of Bayer's ReadRite® products. Here we report on the progress we have made in each of these business segments.

### **Diagnostic products for chronic respiratory disease**

We are applying our expertise in sputum processing and our patented diagnostic test device to pioneer the development of simple sputum-based diagnostics for use at point-of-care.

There are currently no rapid diagnostic tests that accurately describe the underlying pathology of chronic lung disease, making it difficult to provide effective treatment. Tyrian has already established assays for a number of key sputum-based markers of chronic lung disease on its DiagnostIQ™ platform. We have now defined a clinical need for a simple test that would detect and quantify some of these key markers. Such a test would help to differentiate among the various treatment options for lung conditions such as chronic obstructive pulmonary disease (COPD) and asthma.

We have made several significant developments towards this goal.

- We have proved that sputum provides better results than blood as a test sample for evaluating the pathology of lung disease. Changes in the levels of certain markers corresponding to different states of lung disease were detected in sputum samples and not in blood samples of the same patients. This is because changes detected in sputum are highly specific to lung disease, while the levels of these markers in blood reflect changes occurring throughout the body.
- The use of sputum as a test sample is not yet routine, and currently requires specialised laboratory facilities and skilled operators. To deal with this issue, Tyrian has developed a novel, rapid, simple and reproducible protocol for sputum processing. This protocol will enable fast results in a clinical setting, with no specific training required. Tyrian's collaboration with Aradigm Corporation has provided access to unprocessed sputum samples that have facilitated these developments.
- To complement this proprietary sample preparation approach, we have developed new design concepts intended to improve the use of the DiagnostIQ™ platform for medical applications. This includes a design for a sputum processing device that could be integrated with the test platform for safer and simpler sample collection and handling.
- We have made major advances in understanding the market opportunities in COPD diagnosis and forged new clinical relationships and collaborations (both within Australia and internationally) through participation in key respiratory disease meetings, including the Thoracic Society ANZ in Perth and the American Thoracic Society Meeting in Denver, USA.

Bringing all of the above developments together, we are currently sourcing and testing a range of clinical samples that should define Tyrian's first proprietary point-of-care test for chronic lung disease.

### **Partnering Tuberculosis biomarker for molecular diagnostic**

With one-third of the world's population infected with tuberculosis (TB), there is a huge global market for accessible, accurate and affordable diagnostic tests for active TB. The problem with current methods used for diagnosing active TB are that they are either accurate and slow (3-8 weeks) or insensitive (~60% detection). Every country needs rapid and effective TB testing to prevent the spread of this highly contagious disease, however the demand and infrastructure for TB testing varies widely among different countries.

This need has been reinforced by recent attention in the media to a new molecular diagnostic test for TB developed by Cepheid. Since this test uses highly sophisticated technology and requires a laboratory environment, it is well suited for use in developed countries, but is currently not easily deployable to many resource-limited settings (WHO Policy statement 2011: ISBN 978 92 4 150154 5) where the incidence of TB is extremely high and growing, such as India and South-East Asia.

Tyrian is in discussions with several companies about incorporating its patented mRNA marker onto their competitive molecular diagnostic platforms, that have been developed for deployment to the major TB markets. There are very few molecular markers, with the sensitivity and specificity required for detection of active TB, available for implementation onto these platforms. An advantage of Tyrian's mRNA marker over the current gold standard RNA marker is that it appears to be present at higher levels in clinical sputum samples, potentially allowing for greater sensitivity at detecting active TB infection.

At the same time, we continue to search for opportunities to commercialise our TB protein markers.

### **Support for the development and marketing of Bayer's ReadRite products**

#### ***Commercialisation of ReadRite-Alpha Amylase (RR-AA)***

The RR-AA test provides a possible alternative to the agriculture industry's standard Hagberg Falling Number (HFN) test for assessing rain-damaged wheat. The RR-AA test offers the advantage over the HFN of being a simple, rapid test that can be used on-site (from farm gate to receival site) to provide a reliable and quantitative measure of wheat quality across multiple sites. Competing with an entrenched industry standard requires sanction from key industry groups. While the product was first launched in Canada in August 2009, market penetration of the product has been disappointingly slow.

Nonetheless, some positive signs are emerging.

ReadRite Alpha-Amylase evaluations undertaken by certification bodies in North America are nearing completion, and these technical evaluations show close correlation to those of the established HFN test. Importantly, further collaborative studies with Bayer have been proposed by these same certification bodies, which could advance market adoption of a new test for accurate on-site assessment of wheat quality. In this, Tyrian continues to support Bayer in its endeavours through the supply of products and technical advice and assistance.

We have commenced the final phase of technology transfer of RR-AA to the commercial manufacturer in Thailand, following the successful completion of three previous validation batches. The achievement of this milestone in August 2011 will complete the outsourcing of manufacture of our DiagnostIQ™ technology.

### ***Development of final prototypes for second ReadRite test***

A second crop quality test for Bayer has been developed by Tyrian for one grain type. While this test initially performed well, we have identified in more extensive testing that one of the performance criteria required for the final product cannot be met using the current reagents. In light of this outcome, Tyrian and Bayer are now reviewing alternatives to meet Bayer's specifications for the product. The next step after successfully overcoming the current issue would be to proceed with the development of prototype tests for field trial evaluations in the EU and North America.

We will continue to report on the status of our programme with Bayer and on the outcomes of discussions with other third parties.

***Disclaimer:*** This announcement includes certain forward looking statements relating to the future expectations, prospects and aims of Tyrian Diagnostics. These types of statements are made in good faith and, in Tyrian's opinion, on a reasonable basis. However, these types of statements are based on certain assumptions and are subject to risks, uncertainties and other factors, which could cause actual outcomes and results to differ materially from future outcomes and results expressed, projected or implied by such statements. Accordingly, Tyrian does not give any assurance that such statements will prove accurate, and actual outcomes and results and future events could differ materially from those anticipated in such statements.

### **About Tyrian Diagnostics Limited**

Tyrian Diagnostics (ASX: TDX) is an Australian-based company that develops and commercialises rapid point-of-need diagnostics. The company has an innovative and proprietary diagnostic test platform, DiagnostIQ™, and Tyrian's current strategy is to partner this technology for the development and commercialisation of clinical and non-clinical diagnostic tests.

The company's first product is a point-of-need diagnostic for measuring wheat quality, ReadRite Alpha Amylase, developed in partnership with Bayer CropScience AG, with a second product under development. Tyrian's longer term plan is to exploit its intellectual property and expertise in respiratory and infectious diseases to achieve higher returns through developing and commercializing clinical diagnostic products.

Tyrian is also seeking to partner its patented biomarkers for final development and marketing of molecular and protein-based diagnostic tests for active tuberculosis (TB)

Additional information about Tyrian Diagnostics can be found at [www.tyriandx.com](http://www.tyriandx.com)

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