



tyriandiagnostics

Taking IVDs to Market
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Overview

- Introduction to Tyrian Diagnostics
- Path to Commercialisation: a case study
- Key points;
 - Engage with the business community
 - Adding value through partnering
 - Outsourcing manufacture of IVDs
 - Cost and risk of time to market vs potential revenues
 - Constraints to getting IVDs to market

Tyrian Diagnostics

- **Developing a pipeline of next generation Point-of-Need (PoN) diagnostic tests**
 - From Proteome Systems (ASX:PXL) to Tyrian Diagnostics (ASX:TDX)
- **Core competitive advantage**
 - DiagnostIQ™ , a proprietary PoN diagnostic platform
- **Capitalising on technology assets to realise near term revenues**
- **Longer term higher value products**
 - respiratory infectious disease, proprietary targets
- **Partnerships for product development**
 - Bayer CropScience AG (crop quality and pricing)
 - Becton, Dickinson and Company (detection of active tuberculosis)

DiagnostIQ™ Platform Profile

Rapid Diagnostic with Broad Potential

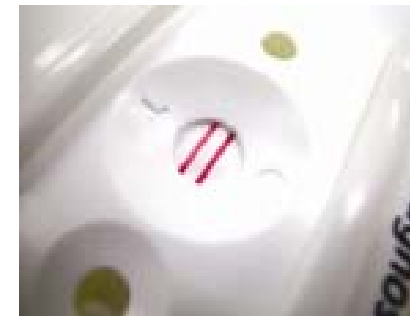
- Will detect any target with a suitable antibody
- Can be used with many types of samples (e.g. sputum, saliva, blood, faeces, urine, plant material)
- Rapid and disposable – 5 minutes for result
- 5 registered patents and 11 pending patents
- Validated with marketed product – ReadRite alpha amylase



1. Add test sample and gold conjugate



2. Press down sample chamber



3. Remove sample chamber, wash & read

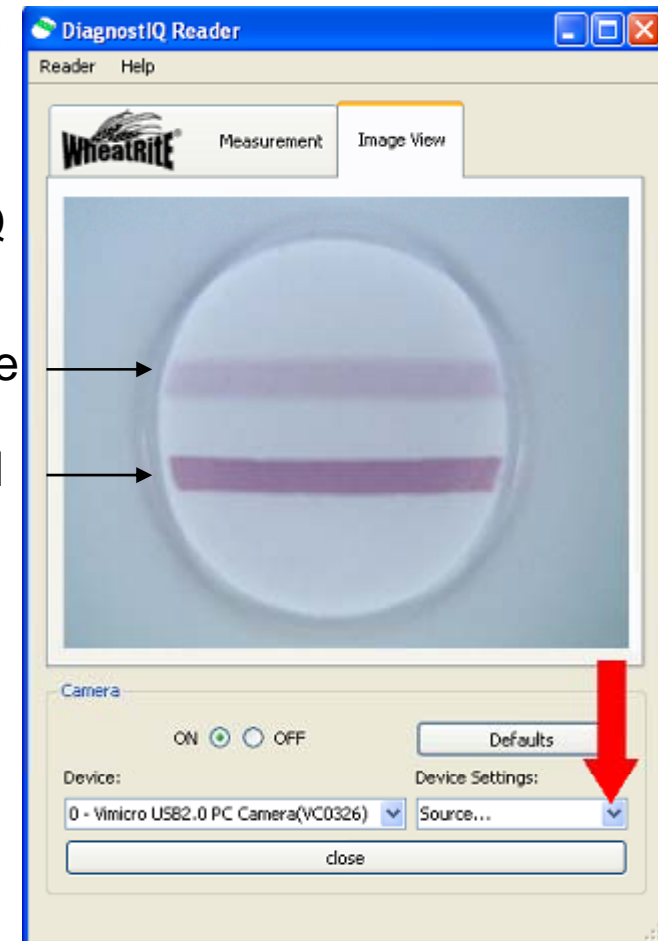
DiagnostIQ Reader: quantitative results

- **D'IQ Reader** - rapid analysis of multiple tests; accurate outputs
- **Manufacture outsourced** to Sydney-based company – TDX earns revenues from sales
- **Reader is central application** for any DiagnostIQ test where quantitative result required



DiagnostIQ Reader compares the test result with a known standard to provide instant, quantitative result

Test sample
Standard



Business Strategy

**Identify and
validate diagnostic
target**

**Existing
3rd Party
diagnostic targets**

and/or

**Tyrian's
proprietary
biomarkers**

**Diagnostic
Product
Development**

**Point-of-need
test format
(DiagnostIQ)**

and/or

**Established
laboratory tests
(e.g. ELISA)**


**Product
manufacture and
marketing**

**License: royalty
payments**

and/or

**Product: sales or
profit share**

Pipeline – DiagnostIQ Products

DiagnostIQ Partnered Products	Application	Discovery and/ or Validation	Proof-of Concept	Product Development	Market Launch
1. ReadRite α -amylase -with Bayer	Alpha amylase wheat quality test				
2. Undisclosed Product - with Bayer	Crop quality test				
3, 4, 5.... Potential additions to pipeline	Agriculture, veterinary or medical...	 Next round of opportunities under evaluation/ negotiation, to be added progressively			
DiagnostIQ Reader Tyrian product	Accompanies DiagnostIQ tests				

First product in market: ReadRite® alpha amylase test

- Point-of-Need test to assess wheat quality – co- branded Tyrian and Bayer
- Independent evaluation by key industry organisation confirmed accuracy and high performance of test
- Tyrian has completed manufacture for first roll-out in North America



WheatRite test re-branded as ReadRite® alpha-amylase test

Path to Commercialisation: a case study

Wheat alpha amylase test

Phase 1:

- 2002 Approached by C-Qentec (subsidiary of Bayer CropScience)
- 2003-05 Developed test using C-Qentec's Ab and Tyrian's DiagnostIQ platform
- 2006 Bayer CropScience Australia rights to manufacture & market the test

Phase 2:

- 2007 Approached Bayer re commercialisation plan for the WheatRite test
- 2008 Development and Licensing Agreement with Bayer CropScience AG
- 2008 Tyrian to undertake manufacture of test with support from Bayer AG
- 2009 First sales and global marketing of test by Bayer AG
- 2009 Second product in development with Bayer AG

Path to Commercialisation: issues to consider

- Engage with the BD community
- Co-investment: a mutual advantage
- Does the product meet expectations
- Outsourcing manufacture of IVDs
- Cost and risk of time to market vs potential revenues
- Constraints for biotechs to commercialise IVDs

Engage with the Business Community

Use available resources, e.g. industry specialists, investment fund managers, manufacturers, consultants, user groups to:

- Determine product viability
- Determine scope of product opportunity
- Formulate partnership strategy
- Feedback on competitors
- Define competitive advantage
- Introductions to partners

Adding value through partnering

Advantages to Bayer

- Not core business
- Same partner for development & manufacture
- Multiple products on same platform
- New technology developed & qualified for manufacturing

Advantages to Tyrian

- Provides revenue stream
- Control of product IP
- Control of manufacturing partner & technology transfer process
- Sales forecasts offset cost & risk of outsourcing manufacture

Build and maintain relationships at multiple levels to identify the people and the pathway for decision making

Industry acceptance

- Know your user and their environment i.e. human health practitioners, home patients, farmers, vets
- Understand what drives user acceptance, i.e. quicker, easier, cheaper, sensitivity, point of care
- Define early in the development process the industry standards, guidance and regulations required for formal industry acceptance as 'gold standard'

Outsourcing manufacture of IVDs

- Careful planning is key
- Effective purchasing controls – finding the right partner
- Ensuring no contractual supply conflicts exist between customer e.g. Bayer and outsourced manufacturer expectations
- Robust design for manufacturing and assembly
- Identify and manage manufacturing process risk
- For efficient outsourcing, product must be in ‘design freeze’
- Effective document and record control procedures
- Product volumes versus pricing structures

The cost of time (to market vs returns)

- Planning and implementation – go/no go decisions
- Quality processes (design, manufacturing, testing, product development, etc)
- Risk management – design and process
- Project budget
- Resourcing the right people
- Aligning teams with project objectives

Constraints for commercialising IVDs

- Sourcing experienced people in Australia
- Supply chain e.g. manufacturing, distribution
- Competitive product pricing
- Accessing global market in changing regulatory framework (Asia and US, Europe)
- Higher entry barriers (regulatory) in bringing new technologies to market
- Government support

Summary

- Take time to build the right team
- Effective and detailed planning up front reduces risk and costs
- Design for the user, not for yourself
- Quality products are key for success
- Understand the changing nature of the regulatory framework
- Consider strategy for establishing product pricing