



tyriandiagnostics

Commercialising IVDs in a Changing Regulatory Framework

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Business Overview

- Tyrian is a diagnostics company developing a pipeline of next generation Point-of-Care (“PoC”) diagnostic test products
- The PoC diagnostics market is an \$11.3b industry, which industry experts predict will grow by 10% – 12% p.a.
- The Company’s near term strategy is to deliver revenues through the commercialisation of products using its patented DiagnostIQ™ platform and third party validated diagnostic targets
- Tyrian controls the manufacture of its DiagnostIQ products
- Longer term, the Company will develop higher value medical diagnostics based on proprietary Tyrian targets, to capture a greater share of sales revenues

Company evolution

- The Company started out as a developer and manufacturer of analytical instrumentation and integrated technologies
- In 2005 the Company transitioned into an R&D business
 - Biomarker discovery for diagnostics
 - Acquisition of a portfolio of small molecule compounds
- Today, Tyrian is a Point-of-Care (“PoC”) diagnostics company with an IP portfolio comprising:
 - Biomarkers
 - Antibodies
 - Sample processing
 - Diagnostic technology

Changing regulatory requirements in alignment with the business

- **Instrument business**
 - Designed, developed, manufactured instruments to standards EN61000, EN6010-1 and EN61326
- **R&D business**
 - Introduced ISO 17025 in 2007
 - Only commercial R&D IVD company in Australia to be NATA accredited
 - Systems in place to deliver quality research outcomes to partners
- **Diagnostics business**
 - Implementing ISO 13485 for developing and preparing the business to commercialise clinical IVDs
 - This is the accepted standard for GMP

Impact of these changes on the business

- **Business strategy dictates regulatory requirements**
 - Cultural change - adaptable and cross-functional teams
 - Right resources - in-house expertise and networks
 - Steep learning curve for the whole organisation - different mindset, understanding and discipline
 - Cost for implementation and maintenance - gradual transition
 - Planning for change implementation - alignment of company activities and teams
 - Timelines - short term and long term strategy

▪ Challenges

- Ag → clinical
- Manufacture in-house → qualified OEM
- Partnered products → proprietary products
- No regulatory framework (Ag) → sophisticated regulatory framework (clinical)
- No go-to-market costs → go-to-market costs

Product Pipeline

	Product	Partner	Discovery and/or Validation	Proof-of Concept	Product Development (with *Reg Approval)	Market Launch	
3rd Party DiagnostIQ™ Targets	ReadRite alpha – amylase	Bayer CropScience	[Progress bar spanning Discovery, PoC, and Product Development]				
	Crop quality test	Bayer CropScience	[Progress bar spanning Discovery and PoC]				
	New products	In progress	[Small green bar]	Next round of opportunities under evaluation, to be added progressively			
Proprietary Targets	DiagnostIQ Reader	Tyrian Diagnostics	[Progress bar spanning Discovery, PoC, and Product Development]				
	TB PoC test*	TBD	[Progress bar spanning Discovery and PoC]				
	TB molecular test*	TBD	[Progress bar spanning Discovery and PoC]				
	Project RD001*	Internal development	[Small purple bar]				

DiagnostIQ™

- Rapid, vertical flow, qualitative or quantitative Point-of-Need test, for detection and monitoring of diagnostic targets.
- Format suitable for use with complex samples e.g. blood, sputum, faeces, ground grains
- Patent protected

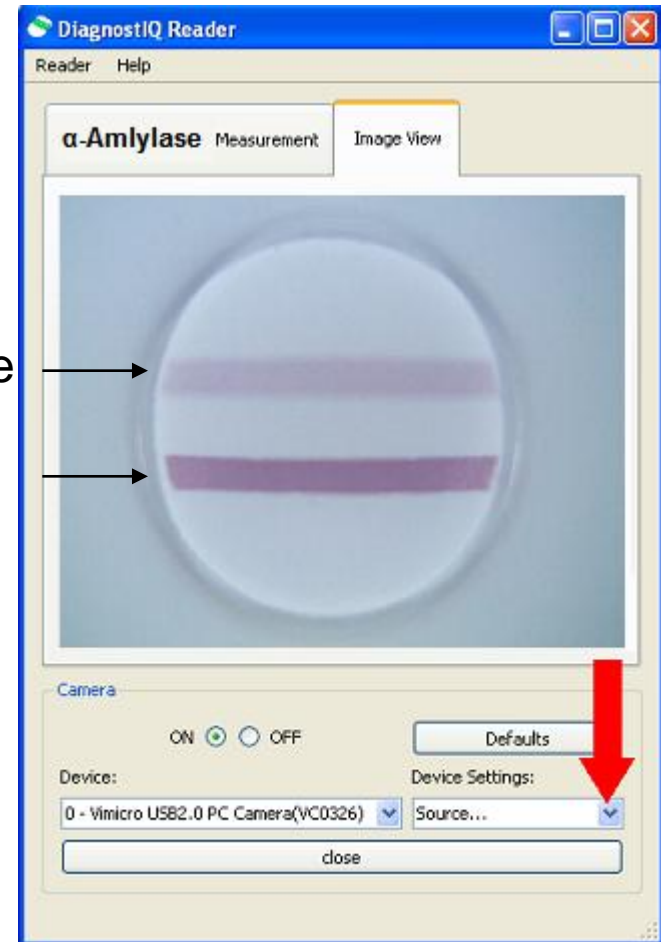


DiagnostIQ™ Reader

- DiagnostIQ Reader compares the test result with a known standard to provide an instant quantitative result
- Currently used for Ag applications, but applied the following standards: EN61000-4-3 and MIL-STD 461E against Directives 89/336/EEC (EMC); 2006/95/EC (LV), 2002/96/EC (WEEE) and 2002/95/EC (RoHS)



Test sample
Standard



Commercialising Tyrian's IVD products

- **Agriculture IVDs**
 - Currently no regulatory requirements
 - Key industry organisations validate IVDs
 - No harmonisation (multiple validation studies, expensive!)
- **Clinical IVDs**
 - Identify product standards for 'intended use'
 - In EU, harmonised standards
 - In USA, consensus standards
 - In Australia, adopting IVDs into the current Act



ReadRite-Alpha Amylase

Tyrian's transition to clinical products

▪ **Process**

- Training, training, training
- Gap analysis between requirements for ISO17025 to ISO13485
- Audit current practice – identify shortcomings
- Plan and implement improvements to current practice (common to ISO 17025 and ISO 13485)
- Develop and implement new practices for ISO 13485 (ownership - system has to work according to company culture, finances, etc.)

▪ **Product**

- Ag -> clinical
- Customer specifications -> regulations, guidelines and product standards
- Understand 'intended use' to define performance and product risk classification
- Develop regulatory plan for all intended product markets

- **In-house**

- Scientific laboratory
- Manufacturing not scalable
- Poor process flow and facility constraints
- Not cost effective
- Dilutes focus and innovation for new products

- **Outsourced**

- Few PoC IVD manufacturing companies certified to ISO 13485
- Difficult to translate unique processes into a specification
- Capacity vs required production volume
- Manufacturing processes manual vs automation
- Time and cost to achieve desired production efficiencies

What is driving change in IVD regulatory framework?

- **Many products in market e.g. influenza tests**
- **IVD PoC tests becoming more sophisticated with fully quantitative results**
- **Healthcare costs continue to rise, creating new opportunities**
 - Early diagnosis for effective intervention & monitoring disease
 - Diagnostics with actionable results e.g. predictive of therapeutic response
- **Trend toward personalised medicine**
 - Improved diagnostic efficacy
 - Role of the internet as a health education tool
 - Segmentation of patients for therapies
- **Changing regulatory requirements for IVDs is onerous for small diagnostic companies, however it:**
 - offers better protection for the consumer
 - ensures higher quality & better performing products
 - enhances the value of diagnostic products