



POINT OF CARE | CLINICAL LABORATORY

**Your Diagnostics Partner**  
**March 2018**



**Nasdaq: TRIB**

## Overview

- Founded in 1992 – quoted on NASDAQ (TRIB)
- Headquartered in Bray, Ireland (favourable tax regime – 12½% corporation tax)
- Significant operations in the USA – direct salesforce; in addition to manufacturing operations in Buffalo, Jamestown, San Diego and Kansas City
- Direct sales operation in Brazil
- Leading positions in a number of high-growth segments

# Revenues

- \$99m revenues in 2017
- Key business segments:
  - Diabetes
  - Point of Care - HIV/Malaria/Syphilis
  - Infectious diseases
  - Autoimmune
  - Life science supply

# Diabetes

- Revenues \$30m
- Market Size \$300m. Worldwide market share - 10%
- A1c is a long term indicator of diabetes management
- A1c diabetics require A1c testing 4 times a year
- Major increase in incidence of diabetes in USA and internationally
- Significant haemoglobin variant and neo-natal revenues also
- Major growth market – 12% p.a.
- Competitive landscape
  - BIO-RAD
  - Arkray
  - Tosoh
  - Trinity Biotech



# Premier

- Premier – clinical lab HbA1c instrument - FDA approved in December 2011
- **State of the art instrument**
  - interference free (boronate affinity)
  - quicker – 1 minute assay
  - biggest capacity - 210 tests
  - leading edge software (touch screen)
  - modular configuration (ease of service)
- **Market**
  - Europe – Menarini (40% Market Share)
  - USA - Direct salesforce
  - China (approved 2013)
  - Brazil (approved 2014)



## Premier Placements

Year	Placements	Key development
<b>2012</b>	202	Initial product launch in USA, Europe and other strategic markets
<b>2013</b>	321	First sales in China – 74 instruments
<b>2014</b>	460	First sales in Brazil – 121 instruments
<b>2015</b>	350	Temporary withdrawal from Brazilian market due to significant fall in local currency
<b>2016</b>	320	
<b>2017</b>	311	
<b>Total</b>	1,964	

# Premier Resolution

- Haemoglobin Variant version of Premier launched in 2016
- Market size \$100m
- Tests for haemoglobin abnormalities such as Sickle Cell and Thalassemia
- Current variant library includes 200 different variants – continuously being expanded
- Instrument has all of the advantages of the Premier A1c instrument in terms of speed, capacity, interactive software and maintenance
- Key markets
  - Europe – especially Mediterranean region (Menarini)
  - Turkey (Beckman Coulter)
  - Middle East
  - USA – awaiting FDA approval (existing Ultra business \$5m)
  - China & Brazil – awaiting regulatory approval

## Point of Care

- **HIV**

- Public Health market in USA
- Confirmatory test in Africa
- Screening test in Africa - **new test launching 2019**

- **Malaria**

- Screening test in Africa - **new test launching 2019**

- **Syphilis**

- Public Health market in USA
- Screening test for International markets - **new test in development**



## HIV – USA Market

- Market Size of \$35m
- Trinity Revenues \$5m p.a.
- Blood tests
  - Trinity Biotech
  - Orasure
  - Chembio
- Saliva test
  - Orasure
- Strong gross margins
- Market is declining due to constraints on public expenditure



## HIV – African Confirmatory Market

- HIV testing in African mainly funded by USA, EU and other developed countries
- President's Emergency Plan for AIDS Relief ('PEPFAR') - over \$30 billion to date
- WHO, World Bank, Clinton & Gates Foundations
- Specific testing algorithms used in each country
  - Screening
  - Confirmatory
  - Tie-break
- Gold standard product – confirmation test in 95% of Africa
- Trinity's Uni-gold test on the market for over 20 years (revenues in excess of \$11m)
- Reputation as highest quality test commanding premium price

## HIV – African Screening Market

- Market size \$135m (equates to c.170m tests)
- Market dominated by Determine (Abbott/Alere)
- Principal market – Sub-Saharan Africa (e.g. Nigeria, Kenya, Ehtiopia, Tanzania and South Africa)
- Trinity targeting this market segment given the higher volumes – need different test to Uni-gold confirmatory test
- New TrinScreen test has been developed - currently undergoing trials in Africa
- Expect to launch in 2019 following WHO approval
- Low cost automated manufacturing plant established in Dublin, Ireland

## Malaria

- Market size - in excess of 300m tests p.a.
- Market leaders AccessBio, Abbott, Premier
- 90% of global malaria cases occur in Africa
- Major markets in Western Africa (incl. Nigeria)
- Lower price market compared to HIV
- Trinity has new test at an advanced stage of development – exceeds market leader performance
- Will leverage off Trinity's reputation in the HIV market
- Expect to launch in 2019 following WHO approval
- Low cost automated manufacturing plant established in Dublin, Ireland

# Syphilis - Rapid Syphilis Test

## USA

- CLIA waiver received in December 2014
- Only FDA approved rapid syphilis test on the market
- Customers: - State and city public health departments
  - CDC funding
  - Planned parenthood and community based organisations
- Excellent companion product for Trinity's HIV test
- Revenues currently \$1-2m p.a.

## Rest of World

- Trinity developing a low cost syphilis test for the rest of world market
- Target launch date 2020

# Infectious Diseases

- Broad infectious diseases product range – 60 products
- Lyme - dominant market share of U.S. confirmatory business
- Prominent niche player – esoteric tests
- Large DSX instrument installed base in USA – reagent rental
- China – large growth market
- POC tests : H. Pylori, LUA, Strep. Pneumo, HSV



## Autoimmune

- \$20m revenues. Buffalo, New York manufacturing facility
- \$250m speciality autoimmune market growing 10% annually, main competitors –Werfen-Inova (\$75m), Bio-Rad (\$70m) and Phadia (\$40m)
- Autoimmune products: Lupus, Sjögren's, Celiac, Crohn's and Rheumatoid Arthritis
- IFA products (best in market), EIA products (competitive with market leaders)
- Reference laboratory (NYSDOH accredited lab) – autoimmune testing
- Growth since acquisition has come from the Immco reference laboratory – from new tests (e.g. Sjögren's) and increased testing to Quest/Lab Corp
- Enhanced instrumentation offering required to drive product sales

## Autoimmune – IFA Instrument

- Increasing market demand for total IFA automation
- Customers looking for systems allowing “walk-away” testing with higher throughput
- Automated pattern recognition reduces the need for human intervention
- Target customers : medium-large laboratories
- Main target markets: North America, South America (especially Brazil), China and Middle East
- Main competitors: Bio-Rad (Bio-Plex); Inova (Bio-Flash)
- Trinity has partnered with an instrument manufacturer to develop a new automated reader and processor
- Projected launch date 2020



## Financial Highlights

- Revenues of \$99m in 2017 – represents underlying growth of 3%
- Operating profit of \$5.5m in 2017
- Generating EBITDA of approximately \$11.5m p.a.
- Cash of \$57.6m on hand (exchangeable note of \$115m)
- Undertaking major share buyback programme following recent fall in share price. 2.3m shares purchased (\$17m) in last 2 years

## Financial Information - Profit and Loss

	2016 \$m	2017 \$m
Revenue	96.6*	99.1
EBITDA	15.0	11.5
Operating Profit	7.5	5.5
Profit after tax	3.6	2.3
Diluted EPS (US cents)	29	26

*Amounts above exclude non-cash financial income/charges and once-off items*

- \* At the end of 2016 older Clinical Laboratory products were culled. 2016 revenues including culled products were 99.6m.

## Financial Information – Balance Sheet

Balance sheet as at 31 December 2017	\$m
Fixed assets	5.8
Trade and other receivables	22.2
Inventory	32.8
Cash	57.6
Current assets	112.6
Trade and other payables	(21.2)
Net current assets	91.4
Convertible loan notes*	(115.0)

\* \$115m raised through issuance of convertible loan notes in April 2015. This is shown net of fair value adjustments and transaction costs in Press Release Balance Sheet.

## Take Aways

- Strong point of care growth potential. New tests for HIV, Malaria and Syphilis
- Profitable and cash generating infectious disease lab business
- Strong haemoglobins product offering - 311 Premier placements in 2017, new variant version being rolled out
- Growing autoimmune business (Immco) – including Sjögren’s opportunity.  
New automated IFA instrument in development
- Cash of \$57.6m at 31 December 2017
- 12½% tax rate – Ireland