



POINT OF CARE | CLINICAL LABORATORY

**Your Diagnostics Partner
October 2019**



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

Revenues

- \$97m revenues in 2018
- Key business segments:
 - Diabetes
 - Point of Care - HIV/Malaria/Syphilis
 - Autoimmune
 - Infectious diseases
 - Life science supply

Diabetes

- Revenues \$33m
- 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 – clinical lab HbA1c instrument - FDA approved in December 2011
- **State of the art instrument**
 - interference free (boronate affinity)
 - quicker – 1 minute assay
 - largest 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
2012	202	Initial product launch in USA, Europe and other strategic markets
2013	321	First sales in China – 74 instruments
2014	460	First sales in Brazil – 121 instruments
2015	350	Temporary withdrawal from Brazilian market due to significant fall in local currency
2016	320	
2017	311	
2018	317	
Total	2,281	

Premier Resolution

- Haemoglobin Variant version of Premier
- 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
 - USA – FDA approval expected in H1, 2020 (existing Ultra business \$5m)
 - Europe – 30 placements (Menarini)
 - China – approval pending
 - Brazil – we hold 60% of the neo-natal market

Tri-Stat

- New point-of-care A1c instrument developed – launched in 2018
- High levels of precision – CVs of 2-3%
- Serves lower throughput A1c market – smaller hospitals & clinics.
- Also acts as a cost effective back-up to higher throughput Premier instruments
- Mainly targeting markets outside USA and Europe focusing on Latin America, Middle East, South East Asia and Africa
- Submitted for approval in Brazil
- Placements of 150 in 2018, rising to 500 in 2019 with an annual target of 1,000-1,500 instruments p.a.
- Instrument selling price of \$2,500, annual reagent pull through of \$3,000 p.a.



Point of Care

- **HIV**
 - Public Health market in USA
 - Confirmatory test in Africa
 - Screening test in Africa - **new test launching 2020**
- **Malaria**
 - Screening test in Africa
- **Syphilis**
 - Public Health market in USA
 - Screening test for International markets

HIV – USA Market

- Market Size of \$35m
- Trinity Revenues \$4m 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 (Uni-Gold)

- 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 85% of Africa
- Trinity's Uni-Gold test on the market for 15 years
- Reputation as highest quality test commanding premium price

HIV – African Screening Market (TrinScreen)

- Market size \$150m (equates to c.180m tests) (Abbott 140m 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 H2, 2020 following WHO approval
- Low cost automated manufacturing plant established in Dublin, Ireland

HIV – African Screening Market (TrinScreen)

- High quality product
- Will leverage Trinity's excellent market reputation
- Low cost manufacturing
- Abbott management
- Will focus on taking significant market share

Malaria

- Market size - in excess of 300m tests p.a. (270m P.f, 30m P.f/Pan)
- 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 2020 following WHO approval
- Low cost automated manufacturing plant established in Dublin, Ireland

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 Products

- \$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)
- IFA products (best in market), EIA products (competitive with market leaders)
- IFA Products – ANCA, nDNA Crithidia, ANA Hep-2, DFS-70 KO and broad range of tissue slides
- EIA products – Celiac, dsDNA, Cardiolipin, Rheumatoid Factor
- LIA products – ANA, ANA advanced, Myositis, HSP-70, Liver panel
- New expanded manufacturing facility established in Buffalo

Autoimmune - Laboratory

- Reference laboratory (NYSDOH accredited lab) – autoimmune testing
- Major growth driver
 - due to new tests (e.g. Sjögren's)
 - increased testing for Quest/Lab Corp
- International expansion opportunities – in the process of developing a partnership with a Chinese reference laboratory
- Future growth will come from enhanced marketing efforts and broader testing menu. Also pursuing new areas such as CRO services.
- Also supports R&D activities – access to samples etc.

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 competitors: Helios (Aesku/Grifols); Zenit Pro (Menarini/Bio-Rad)
- Trinity is developing an integrated and automated processor and reader
- Will launch in two stages (i) microscope/image reader (ii) automated processor
- Take advantage of best-in-class IFA slides
- Projected launch date 2020

Financial Highlights

- Revenues of \$97m in 2018
- Operating profit of \$6.7m in 2018 – increase of 22%
- Generating EBITDA of approximately \$12.1m p.a.
- Cash of \$30.3m on hand at 31 December, 2018 (exchangeable note of \$99.9m)

Financial Information - Profit and Loss

	2016 \$m	2017 \$m	2018 \$m
Revenue	96.6*	99.1	97.0
EBITDA	15.0	11.5	12.1
Operating Profit	7.5	5.5	6.7
Profit after tax	3.6	2.3	2.4
Diluted EPS (US cents)	29	26	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 30 September 2019	\$m
Fixed assets	92.1
Trade and other receivables	26.0
Inventory	30.0
Cash	25.1
Current assets	81.1
Trade and other payables	(25.9)
Net current assets	55.2
Convertible loan notes	(99.9)

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 - 317 Premier placements in 2018, Premier Resolution (variant) being rolled out & new Tri-Stat instrument (POC)
- Growing autoimmune business (Immco) - New automated IFA instrument in development
- Cash of \$25m at 30 September 2019