



Nasdaq: TRIB



Trinity Biotech

**Corporate
Presentation**

September 2021

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Key Highlights & Business Model

Key Highlights

- Trinity Biotech develops, manufactures and distributes a diversified range of diagnostic products across the globe.
- Focused on high quality niche diagnostics with differentiated technology to build sustainable revenue.
 - Haemoglobins:
 - Diabetes HbA1c & Haemoglobin Variants.
 - Autoimmunity:
 - Lab – Proprietary Sjögren’s Test.
 - ScopeSmart – AI Automated Testing Instrument.
 - Point Of Care (“PoC”):
 - HIV – Africa – PoC revenue expected to significantly increase in Africa over the next 5 years with the pending approval of TrinScreen HIV from the WHO.
 - COVID-19 Rapid - 12-minute, lateral flow antigen test in development.

Business Model

- Key growth catalysts in Haemoglobins, Autoimmunity & Infectious Disease PoC.
- Company also has 2 niche steady state businesses with significant recurring revenues which add scale and provide low risk diversification:
 - Fitzgerald – a speciality life sciences supply business.
 - Clinical Chemistry – supply of high value, niche, clinical laboratory diagnostic biologicals.
- Revenue base has shifted away from commoditized legacy ELISA Infectious Disease technology over the past years.
- COVID-19 provides an upside but the Company is not dependent on COVID-19 related products – new products in the pipeline that address COVID-19 testing:
 - Active Infection – Rapid PoC Antigen Test.
 - Long COVID – Autoimmunity Lab.

Company Snapshot

Overview

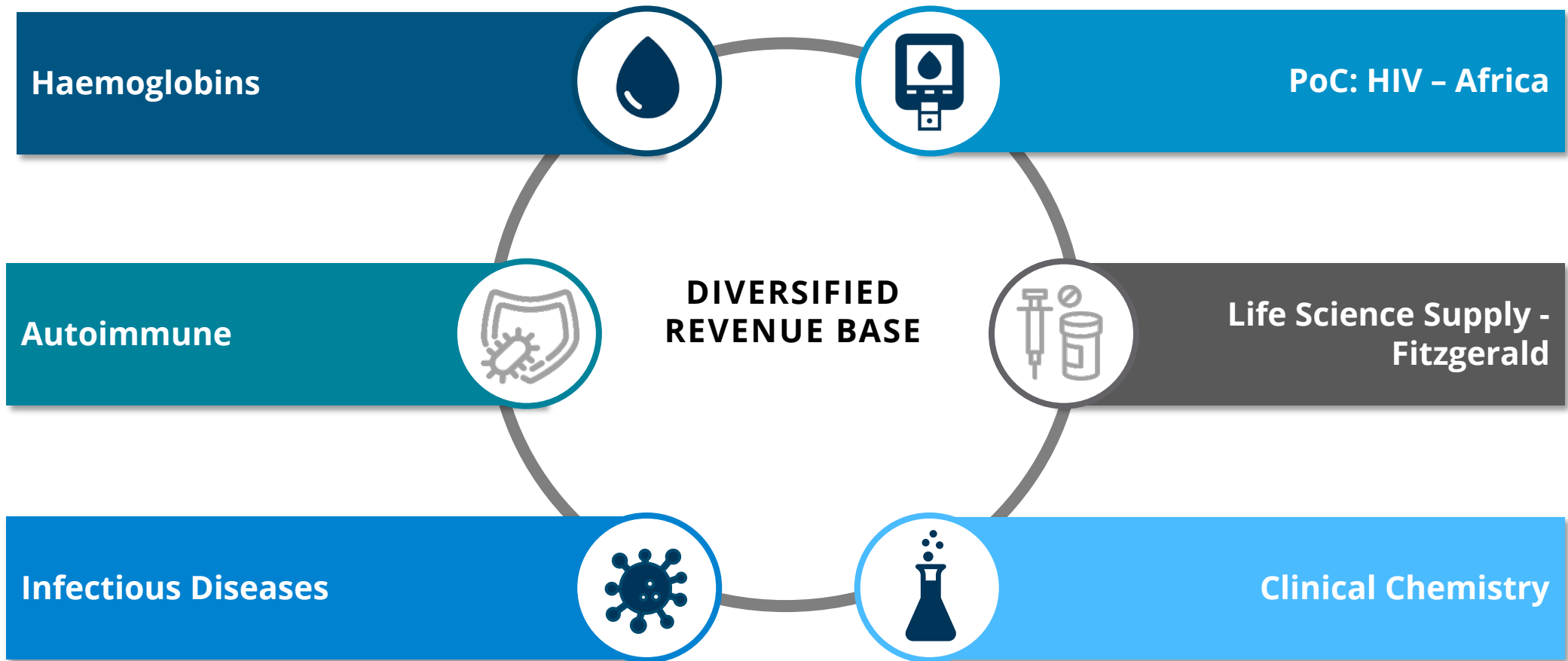
- Founded in 1992 – quoted on NASDAQ (TRIB), headquartered in Ireland.
- Full-service diagnostics development, manufacture & distribution.
- ~ 500 Employees
- Extensive sales infrastructure, mix of direct sales including US, Canada and Brazil, distributor network in approx. 100 countries including broad and long-standing channel reach across Africa.
- Strong U.S. orientation
 - ~ 60% of revenues in the Americas (mainly U.S.).
 - ~ 60% of employees based in U.S.
 - U.S. dollar denominated financials.
- Significant recurring revenue component.

Key Financial Metrics ⁽¹⁾	2018	2019	2020
Point-of-Care Revenues (USD: \$m)	14.8	11.4	9.2
Clinical Laboratory Revenues (USD: \$m)	82.2	79.0	92.8
Revenues (USD: \$m)	97.0	90.4	102.0
Gross Margin %	42.7%	42.2%	47.6%
Operating profit before impairment charges, discontinued operations and once-off items (USD: \$m)	6.7	5.3	20.3

Note: (1) Financials reported in USD in accordance with the provisions of accounting standards under IFRS

Product Lines

Six Main Segments



Growth Catalysts

Focused on Selected Diversified Underlying Growth Catalysts



Haemoglobin: Diabetes

- The number of **people with diabetes** rose from 108m in 1980 to **422m in 2014**¹.
- Between 2000 and 2016, there was a **5%** increase in premature mortality from diabetes¹.
- Prevalence has been rising more rapidly in low- and middle-income countries¹, which are focus markets for Trinity (e.g., Asia and Africa).



PoC HIV: Africa

- There were an estimated **38m people living with HIV** at the end of 2020².
- **Over two thirds** of all people living with HIV live in Sub-Saharan Africa (25.4m)² where Trinity has a strong presence and reputation with its HIV products.
- The population of Sub-Saharan Africa is forecast to grow from 1.1 billion in 2020 to 1.5 billion, an increase of ~ 400 million people, in the next 10 years. Management of the HIV pandemic is predicated on diagnosis and treatment.



Autoimmune Diseases

- **Nearly 4% of the world's population** is affected by one of more than 80 different autoimmune diseases³ (~312m people, based on estimated 7.8 billion world population as of March 2020⁴).
- Percentage of the **adult population diagnosed with autoimmune diseases** in 2019 across countries was **7% in the US**, 6% in Europe, 5% in China, 3% each in Brazil and Russia and Japan 2%⁵
- Infectious diseases have long been considered as one of the triggers for autoimmune and auto-inflammatory diseases, recent evidence supports an increase in autoimmune like disease following COVID-19 infection including Long Covid Autoimmune Disease.

Notes:

(1) World Health Organization / <https://www.who.int/news-room/fact-sheets/detail/diabetes>

(2) World Health Organization / <https://www.who.int/news-room/fact-sheets/detail/hiv-aids>

(3) National Stem Cell Foundation / <https://nationalstemcellfoundation.org/glossary/autoimmune-disease/#:~:text=Term%20%2F%20Autoimmune%20Disease&text=Nearly%204%25%20of%20the%20world's,Crohn's%20disease%2C%20psoriasis%20and%20scleroderma>

(4) 2020 World Population Data Sheet / <https://interactives.prb.org/2020-wpds/>

(5) Autoimmune Disease Diagnosis Global Market Report 2020-30 / https://www.reportlinker.com/p05932642/Autoimmune-Disease-Diagnosis-Global-Market-Report-30-Covid-19-Growth-and-Change.html?utm_source=GNW

Growth Area Focused Product Pipeline

Product	Feasibility	Development	Validation	Regulatory Approval	Launch	Product Area	Target Markets
Haemoglobin /HIV/Autoimmune						Multiple	Global
Tri-Stat 2.0 Dual HbA1c						Haemoglobin - Diabetes	Global
Premier Resolution - Non-USA						Haemoglobin - Variants	Global Ex USA
Premier Resolution - USA						Haemoglobin - Variants	USA
Trinscreen HIV						POC HIV - Africa	Africa
Long COVID Reference Lab Test						Autoimmunity	USA
Late Onset Diabetes Reference Lab Test						Haemoglobin - Diabetes	USA
COVID-19 Rapid Antigen						COVID -19	Global
Syphilis Rapid						Point Of Care	Global
T-10 HbA1c Instrument						Haemoglobin - Diabetes	Global
ScopeSmart						Autoimmunity	Global



Product Overview

Haemoglobins

Haemoglobins Overview



Main Business Components

- HbA1c – diabetes testing (Laboratory and Point-of-Care [“PoC”]).
- Haemoglobinopathies – testing for variants (adult and neo-natal).

Main Products

- Premier 9210 (HbA1c for Diabetes).
- Tri-Stat (HbA1c for Diabetes PoC).
- Premier Resolution (Haemoglobin Variants).
- T-10 (HbA1c for Diabetes - in development).

Recurring Revenue Model

- Instruments require reagents per test & other consumables, available only from Trinity Biotech.
- Several thousand instruments placed globally, strong recurring revenue sales on test reagents/consumables.

Proven Track Record

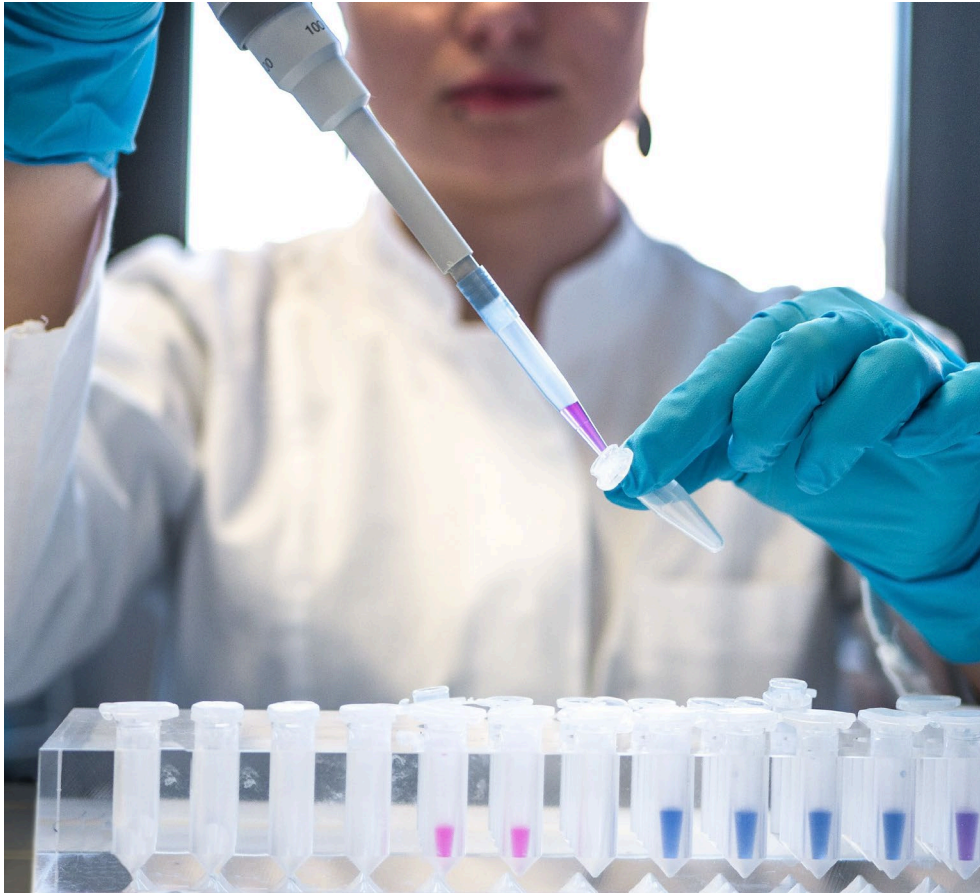
- Demonstrated track record of in-house product development – biologicals, software & hardware.

Laboratory Diabetes (HbA1c) Segment Overview

- HbA1c is a long-term indicator of diabetes management.
 - HbA1c is used for the diagnosis of diabetes and pre-diabetes.
 - Diabetics require HbA1c testing 4 times a year- recurring revenue.
- Major increase in prevalence of diabetes in USA and internationally.
 - World Health Organization – diabetes is a global pandemic.
- Trinity mainly targets mid-throughput HbA1c laboratory market:
 - Premier 9210 – launched in 2011.
 - Developing T-10 instrument to target lower throughput market – see next slide.



New Diabetes Instrument: T-10



Premier 9210 addresses labs that run >5,000 test p.a.

Tri-Stat addresses labs that run <2,500 tests p.a.

- Market opportunity exists in between these instruments i.e. 2,500-5000 tests p.a.
- Have currently partnered with a third-party company to develop the T-10.
- Project involves marrying Trinity's technology and software with our partner's existing instrument chassis.

Expected launch mid 2022.

Large market opportunity in China, Asia, Africa & South America.

PoC Diabetes (HbA1c) Segment Overview

- Targets low throughput HbA1c market e.g. smaller hospitals and clinics.
 - Also acts as a cost-effective back-up to higher throughput Premier instruments.
- Mainly targeting markets outside USA and Europe.
 - Primarily focusing on Latin America, Middle East, Southeast Asia and Africa.
 - These markets are seeing increases in diabetes prevalence due to adoption of Western lifestyle and in many cases their healthcare management systems are geographically dispersed thus lending themselves to a larger number of lower throughput point of care type instruments.
- Opportunity for recurring revenue streams from reagent sales
 - Single use test reagents.
- Tri-Stat 2 Dual Detector launched in late 2020.



Haemoglobinopathies (Variants) Segment

- Tests for haemoglobin variants such as Sickle Cell and Thalassemia.
 - Includes adult and neo-natal screening.
 - Increasing prevalence of the underlying condition globally.
- **New Premier Resolution :**
 - Launched in Europe.
 - Expected US FDA 510(k) approval in late 2021/early 2022.
- Limited competitors in this market.
- In recent years Trinity has gained market share in Brazil through direct sales organization.
 - Significant blood bank screening opportunity.





Product Overview

PoC HIV - Africa

PoC HIV – Africa Confirmatory Market

President's Emergency Plan for AIDS Relief ('PEPFAR') - over \$80 billion to date



Funding

- HIV testing in Africa mainly funded by USA, EU and other developed countries.
- WHO, World Bank, Clinton & Gates Foundations.

Uni-Gold™

- Uni-Gold™ has a reputation as the highest quality product in the market, commanding a premium price.
- Gold standard product – main confirmation test in Africa and on the market for 15+ years.

PEPFAR Relief Plan

- President's Emergency Plan for AIDS Relief ('PEPFAR') - over \$80 billion to date.

Specific Testing Algorithms

- Specific testing algorithms used in each country - Screening, Confirmatory, and Tie-break.

PoC HIV – Africa Screening Market

Africa Screening Market Size Approximately \$150M



Market Size

- Market size \$150m, or c.180m tests, market leader is Determine (Abbott/Alere).

Principal Market

- Principal market – sub-Saharan Africa (e.g. Nigeria, Kenya, Ethiopia, Tanzania, and South Africa).
- Can be used alongside Uni-Gold™ HIV in national algorithms.

New TrinScreen Test

- New TrinScreen test has been developed.
- Submitted for WHO approval in Q1 2021.
- Expected to launch in late 2021/early 2022 following WHO approval.

Automated Manufacturing

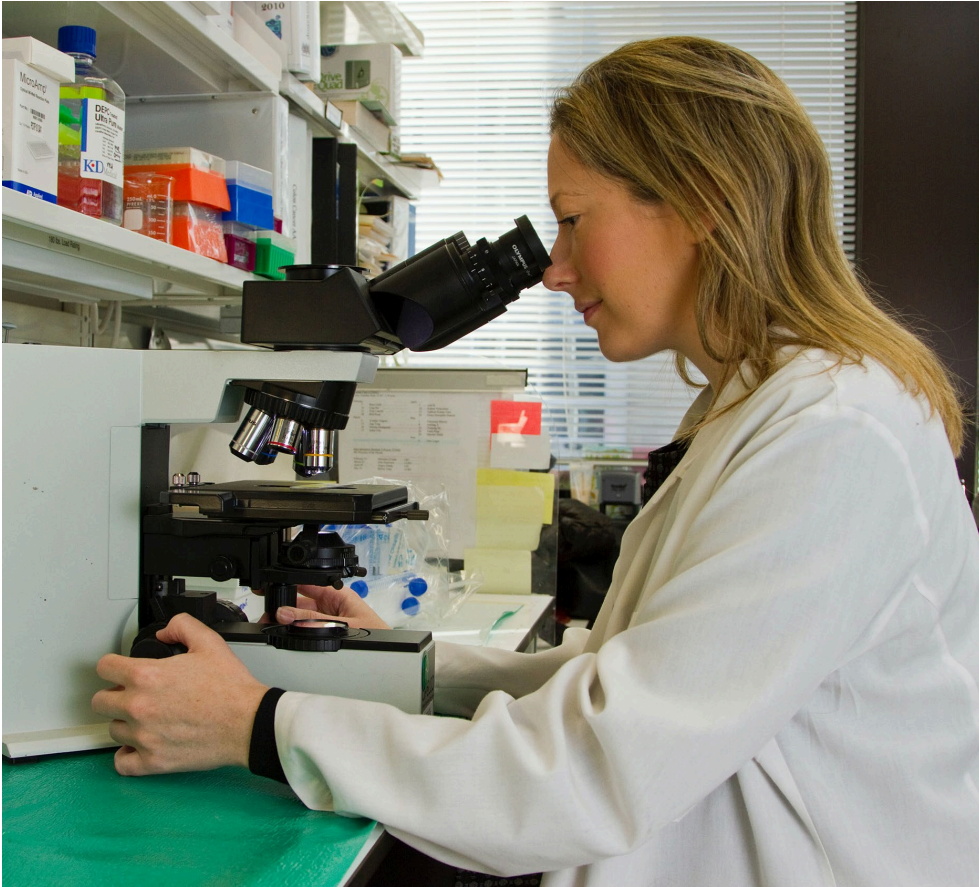
- High throughput automated manufacturing capacity established in Bray, Ireland leveraging existing Uni-Gold HIV manufacturing infrastructure.



Product Overview

Autoimmune

Autoimmune: Reference Laboratory



- **Reference laboratory (NYSDOH accredited lab).
Certifications in the following:**
 - Oral pathology.
 - Diagnostic Immunology (including COVID-19).
 - Immunogenetics (histocompatibility for transplant).
 - Andrology.
- **Major growth drivers:**
 - Sjögren's test (proprietary test for the early markers of Sjögrens syndrome – autoimmune dry eye disease).
 - Expanded testing menu – including Long COVID and Late Onset Diabetes.
 - Also pursuing new areas such as at home testing services.

Autoimmune: Products



- **Immunofluorescence Assay (“IFA”) products – Cryo slides best in market.**
 - IFA Products – ANA HEp-2, DFS-70 KO, ANCA, nDNA and a broad range of tissue slides.
- **Enzyme Linked Immunoabsorbent Assay (“ELISA”) products - competitive with market leaders.**
 - ELISA products – includes Celiac, dsDNA, Cardiolipin, and Rheumatoid Factor.
- **Line Immuno Assay (“LIA”) products – limited competitors.**
 - LIA products - ANA, ANA advanced, Myositis, HSP-70, and Liver panel.

Autoimmune: IFA Instrument (ScopeSmart)

- Developing an instrument to address increasing market demand for total IFA automation.
 - Customers looking for systems allowing “walk-away” testing with higher throughput.
 - Artificial intelligence algorithm for pattern recognition reduces the need for human intervention.
- Target customers: medium-large laboratories.
- Main competitors:
 - Helios (Aesku/Grifols), and
 - Zenit Pro (Menarini).
- Trinity is developing an integrated and automated processor and reader.
 - Expected to launch in two stages; i) microscope/image reader, and ii) automated processor.





Product Overview

Infectious Diseases

Infectious Diseases: COVID-19 Overview



- **Viral Transport Media (“VTM”) – 510(k) approved:**
 - Liquid media tubes with sustaining viral media used to store nasal/throat swab for transport from site of sample acquisition to laboratory for testing.
- **In development – Rapid Antigen COVID-19 test.**
 - Being developed on Trinity’s lateral flow rapid test platform - compatible with existing high volume automated manufacturing capabilities.
 - Expected launch Q2 2022.
- **ELISA for the detection of IgG Antibodies to COVID-19 in human blood samples – CE marked and available for sale in the US.**
 - Utility identifying which members of the population have had a past COVID-19 infection and potential immunity.
 - Utility in monitoring the effectiveness of vaccination programs.

Infectious Disease: Legacy ELISA



Extensive Product Portfolio Built On Enzyme Linked Immunosorbent Assay (“ELISA”):

- ToRCH
- HSV
- MMV
- Syphilis
- EBV
- Lyme

ELISA Is A Legacy Technology:

- US revenues have fallen over time as Western labs transition to newer technologies.
- RoW revenues stable as Asian labs in particular continue to use ELISA technology.



Product Overview

Life Sciences Supply & Clinical Chemistry

Life Sciences Supply & Clinical Chemistry



Life Sciences Supply Overview

- Acquired Fitzgerald Industries in 2004 followed by two bolt-on acquisitions.
- Based in Acton, Boston with approx. 15 employees.
- End customers: Diagnostics companies and academic R&D institutes.
- Selling approx. 3,000 different products (approx. 70,000 products available to sell).

Clinical Chemistry Overview

- Niche esoteric range of products acquired from Sigma Aldrich in 2002.
- Limited number of competitors with equivalent regulatory approvals.
- Manufactured in Bray, Ireland.
- Key Products:
 - G6PDH, ACE, Oxalate and Bile Acid.

Business Overview

Transformation Process

Manufacturing & Operations Transformation



Transforming Trinity Together - transformation program at Ireland manufacturing site.

Ireland site to become a “center of excellence”.

- Being used to develop processes and policies for use throughout the entire Company.
- Goal is to standardize on more modern and cost-efficient operating practices to reduced fixed costs and create more agile manufacturing and operations base.
- Already yielding significant efficiencies.

Transformational Lead - Cormac Reynolds - Director of Operations.

Extensive experience in efficient manufacturing operations for leading industry medical device companies. Formerly:

- Worldwide Director of Pen Needle Manufacturing – Becton Dickinson
- Director of Manufacturing – Ireland – Becton Dickinson
- General Manager – Bray, Ireland – Schering Plough
- Engineering Manager – Bray, Ireland – Schering Plough

Research & Development Process Transformation



TRINovation – R&D process transformation program.

Program Objectives

- Deliver New Products To Market Faster.
- Lower Cost Of Production.
- Capture Profitable Market Share.

Program Focus

- Leverage Direct Customer & Distributor Feedback To Identify Credible Pipeline Opportunities.
- Optimised & Integrated R&D + Manufacturing Readiness + Regulatory Approval Process.

Program Deliverable

- Universal Rapid Test Platform
 - Readily customisable for a broad range of tests.
 - Plug and play model into existing automated manufacturing lines.
 - Multiple component commonalities across different test products, leverage economies of scale in component procurement.

Africa Sales & Marketing Team Transformation

HIV Confirmatory
Market

HIV Screening
Market

Willem Pretorius recently appointed Trinity Biotech President – Global HIV Sales & Marketing

Widely recognized HIV industry sales leader and product innovator. Formerly:

- VP – Strategic Innovation and African Market Expansion – ABBOTT LABS
- VP – Sales – Africa – ABBOTT LABS
- VP Sales – ALERE
- Global Product Director – HIV Care – ALERE

Dedicated to maintaining HIV Confirmatory market leadership in Africa.

Expanding sales force with intent to enter the HIV Screening business.

- Screening market - \$150 million annually - is substantially larger than Confirmatory market.

This new team creates opportunities for further business development in Africa for Trinity Biotech's broader product offering outside of HIV.

Key Global Locations

➤ Ireland: Corporate Headquarters & High Volume PoC Manufacture

- Bray, Ireland

➤ United States: 4 Locations

3 Manufacturing Facilities

- Kansas City, Missouri (Haemoglobins)
- Buffalo, New York (Autoimmunity + Reference Lab)
- Jamestown, New York (Infectious Disease)

2 R&D Centers

- Kansas City, Missouri
- Buffalo, New York

1 Sales & Customer Service Location

- Acton, Massachusetts (Life Science Supply)

➤ Canada: Sales & Logistics Center

- Burlington

➤ Brazil: 2 Locations

1 Sales & Customer Service Location

- Sao Paulo

1 Manufacturing

- Extrema - State of Minas Gerais



Business Overview

Financials

Historical P&L Summary

\$ in 000's	2018A	2019A	2020A
Revenues	97,035	90,435	101,980
<i>% Growth</i>	<i>(2.1%)</i>	<i>(6.8%)</i>	<i>12.8%</i>
Cost of Sales	(55,586)	(52,315)	(53,400)
Gross Profit	41,449	38,120	48,580
<i>Gross Margin %</i>	<i>42.7%</i>	<i>42.2%</i>	<i>47.6%</i>
Other operating Income	102	91	1,860
R&D	(5,369)	(5,325)	(5,080)
SG&A	(29,499)	(27,584)	(25,014)
Operating Profit¹	6,683	5,302	20,346
<i>Operating Profit %</i>	<i>6.9%</i>	<i>5.9%</i>	<i>20.0%</i>
Operating Profit ¹	6,683	5,302	20,346
Add: Depreciation	1,296	2,526	1,674
Add: Amortization	2,825	2,368	1,403
Add: Share-based payments	1,369	758	792
EBITDASO	12,173	10,954	24,215
<i>EBITDASO %</i>	<i>12.5%</i>	<i>12.1%</i>	<i>23.7%</i>

Note: Financials reported in USD in accordance with the provisions of accounting standards under IFRS. The above table is a summary presentation – additional information may be found in the Company's Annual Report on Form 20-F filing filed with the U.S. Securities and Exchange Commission

1) Operating Profit excludes impairment charges, SG&A -closure costs, profit/loss on discontinued operations, SG&A - tax audit settlement – additional information on these items may be found in the Company's Annual Report on Form 20-F filing filed with the U.S. Securities and Exchange Commission.

Balance Sheet

\$ in 000's	12/31/2020A
Inventories	30,219
Trade and other receivables	22,668
Income tax receivable	3,086
Cash and cash equivalents	27,327
Total Current Assets	83,300
Property, plant and equipment	8,547
Goodwill and intangible assets	33,860
Deferred tax assets	4,185
Other assets	355
Total Non-Current Assets	46,947
TOTAL ASSETS	130,247
Income tax payable	154
Trade and other payables	26,488
Provisions	416
Total Current Liabilities	27,058
Exchangeable senior note payable ¹	83,884
Other payables	16,619
Deferred tax liabilities	4,905
Total Non-Current Liabilities	105,408
TOTAL LIABILITIES	132,466
Total Equity/(Deficit)	(2,219)
TOTAL EQUITY AND LIABILITIES	130,247

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1) Exchangeable senior notes having a nominal value of US\$99.9 million mature on April 1, 2045, subject to earlier repurchase, redemption or exchange. The exchangeable notes contain a number of put and call options including a put option which allows the holders to put the exchangeable notes to the issuer at par on April 1, 2022. Additional information relating to the accounting treatment for the exchangeable notes may be found in the Company's Annual Report on Form 20-F filing filed with the U.S. Securities and Exchange Commission.

Senior Management

Ronan O’Caoimh Chairman & CEO

- Co-founded Trinity Biotech in 1992
- 30+ years of experience
- Was previously CFO and then CEO of Noctech Ltd
- Qualified as a Chartered Accountant with Arthur Anderson

John Gillard CFO

- 16+ years of experience
- Previously a senior finance executive at Google and ION Investment Group
- Qualified as a Chartered Accountant and Chartered Tax Advisor with PWC

Dr. Jim Walsh PhD Exec Director – Business Development

- 30 years of experience
- Previously acted as Chief Operations Officer and Chief Scientific Officer
- Holds a PhD degree in Chemistry from University College Galway

Fernando Devia Exec VP, Sales & Marketing

- 30+ years of experience
- Prior to this role was a Director of Sales & Marketing at Hermagen Diagnostics
- Previously a General Manager at Bio-Rad Laboratories

Dr. Terence Dunne PhD Business Development Director

- 16+ years of experience
- Previously Program Manager & Senior R&D Scientist at EKF Diagnostics
- Formerly a Senior Development Scientist at Enzolve Technologies

Cormac Reynolds Director Of Operations, Ireland

- 30+ years of experience
- Previously a Director of Manufacturing at BD and a Manager at Schering-Plough

Trinity Biotech Investment Highlights



01

Pipeline of near to medium term products generated from prior R&D investment

02

Existing diversified diagnostic platform business with annual revenue of USD100m+ in 2020

03

Breadth of capabilities and depth of product areas gives access to large potential whitespace and further growth potential

04

Attractive investment opportunities: Support pipeline new product roll out, build new pipeline to expand target market, access bolt-on or transformative technologies



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