Trinity Biotech

POINT OF CARE | CLINICAL LABORATORY

Your Diagnostics Partner
June 2015

Nasdaq: TRIB

Overview

- Medical diagnostics company headquartered in Ireland.
- 12½% tax rate (Ireland).
- Significant operations in the USA – direct selling force of 60; in addition to manufacturing operations in Buffalo, Jamestown, San Diego and Kansas City.
- Established track record of revenue and profit growth.

Revenues

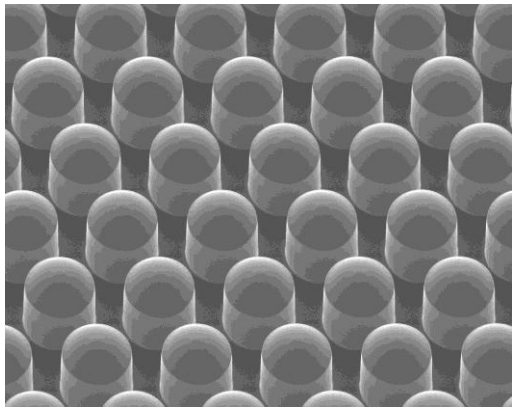
Revenue Breakdown	2010 $m	2011 $m	2012 $m	2013 $m	2014 $m
Cardiac	-	-	-	-	-
Diabetes	19	21	23	27	32
Infectious diseases/Autoimmune	26	29	31	35	43
HIV	16	17	19	19	20
Life Science supply	12	11	10	10	10
Total	**73**	**78**	**83**	**91**	**105**

Cardiac - Fiomi Diagnostics

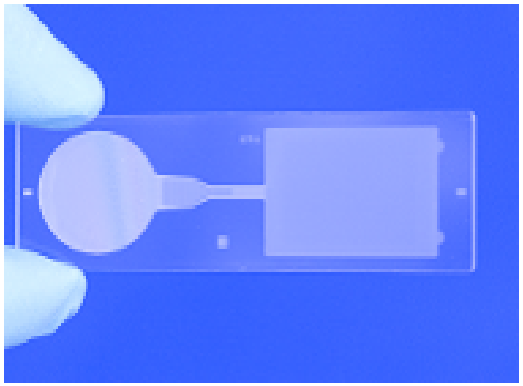
- Acquired Fiomi Diagnostics in March 2012 for $13m.
- March 2012 (7 employees) – since expanded to 35 employees.
- Total project cost - development expenditure, clinical trials and production set-up costs c. $30m.
- Swedish based company – advanced stage of developing a Troponin I test (marker for cardiac arrest) and BNP test (marker for heart failure).

Cardiac - Technology

- Two IP protected components
  - Microfluidic chip - controlled fluid flow giving high assay precision.
  - Optical read-out module – giving high assay sensitivity.
- Superlative sensitivity and precision for Troponin I.
- Platform technology – quantitative instrument.
- Other uses - infectious diseases, autoimmune, allergy, D-dimer, veterinary and industrial.



Micropillar array



Cartridge assembly

Desk-top Reader

Cardiac - POC Market

- Market Size $650m (growing at 12% p.a.).

	Troponin I $m	BNP $m	Total $m
Alere (Biosite Triage)	100	150	250
Roche (Cobas)	60	50	110
Abbott (i-STAT)	120	50	170
Other	70	50	120
Total POC Market	**350**	**300**	**650**
Laboratory Market	**900**	**450**	**1,350**
Total	**1,250**	**750**	**2,000**

- Troponin I FDA approval guidance tightened.
- 3 current point-of-care tests do not meet this guidance.

Cardiac - Timing

- CE Marking / European Regulatory Approval for Troponin received in January 2014.
- European (U.K., Spain, Italy, France, Germany) evaluations ongoing.
- Brazilian evaluation commencing June 2015.
- USA FDA trials in progress at 12 trial sites.
- Following brief cessation, trials recommenced February 2015.

	CE Marking	FDA Submission
Troponin I	Received	August 2015
BNP	Received	September 2015

- FDA approval for Troponin I and BNP expected approximately 6 months after submission
- D-dimer development now commenced.

Diabetes

- $32m Business, 9% market share.
- 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.
- Major growth market – 12% p.a.
- Market Size $300m.
- Competitive landscape
  - BIO-RAD
  - Arkray
  - Tosoh
  - Trinity Biotech

Premier

- Premier – New 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 Q2 2013)
  - Brazil (approved Q1 2014)

Premier Placements

	2012 (Units)	2013 (Units)	2014 (Units)
Menarini	71	119	95
USA	49	62	55
China	-	74	104
Turkey	30	20	20
Brazil	-	-	121
RoW	52	46	65
Total	**202**	**321**	**460**

HIV/Syphilis - HIV

- $20m revenues : $14m Africa & $6m USA ($90m global market).
- Strong gross margins : c.55%.
- **African market**
  - President's Emergency Plan for AIDS Relief ('PEPFAR') - over $30 billion to date
  - WHO, World Bank, Clinton & Gates Foundations
  - Gold standard product – confirmation test in 95% of Africa.
- **USA Market**
  - Market Size of $58m
  - Blood $25m (Trinity $6m; Orasure $10m; Chembio $9m)
  - Saliva $33m (Orasure $33m)
  - FDA approval for HIV-2 claim will boost revenues.

HIV/Syphilis - Rapid Syphilis Test

- CLIA waiver received in December 2014.
- Only FDA approved rapid syphilis test on the market.
- Major CDC support.
- Customers:
  - State public health departments
  - Major city public health departments
  - CDC funding
  - CBO (community based organisations)
  - Planned parenthood
- Excellent companion product for Trinity's HIV test.
- Expected revenues of $2-4m (2015); $4-8m (2016). $10m+ product

Infectious Diseases

- $43m business - strong gross margins and cash generation.
- $9m Lyme confirmation business - 100% market share.
- Broad infectious diseases product range – 60 products.
- Prominent niche player – esoteric tests.
- Large DSX instrument installed base in USA – reagent rental.
- China – large growth market.
- Brazil – approvals awaited.
- POC tests developed: C. Diff, GDH, Crypto, Giardia, H. Pylori, Syphilis, LUA, Strep. Pneumo, HSV.
- $4m blood bank screening (syphilis and malaria), 75% market share of major European markets.

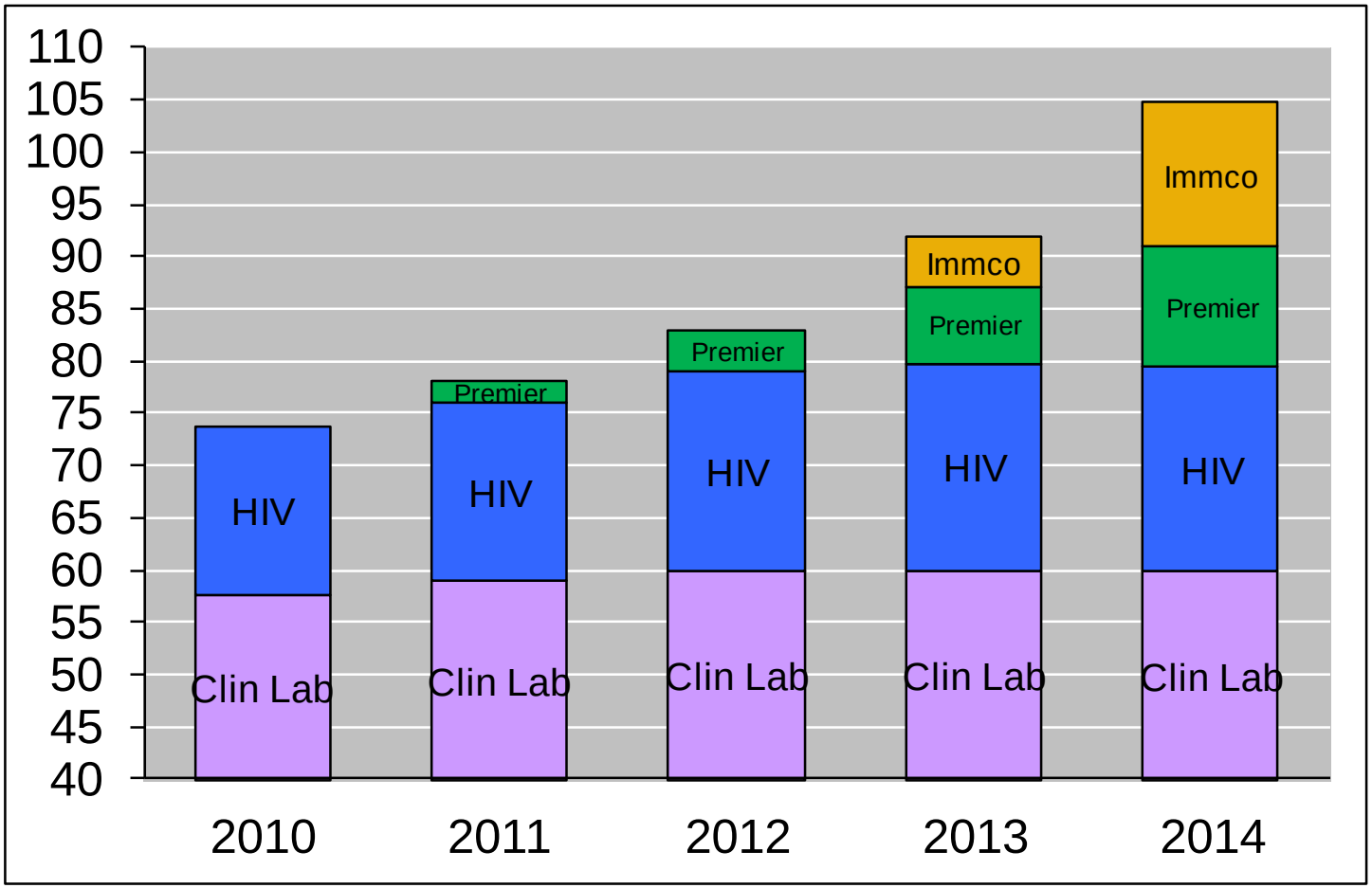
Autoimmune – Immco Diagnostics

- Acquired July 2013 for $33m, based in Buffalo, NY and employing 90 people.
- $250m speciality autoimmune market growing 10% annually, main competitors –Werfen-Inova ($75m), Bio-Rad ($70m) and Phadia ($40m).
- Autoimmune products: Lupus, Sjogren's, Celiac, Crohn's and Rheumatoid Arthritis.
- IFA products (best in market), EIA products (competitive with market leaders) - $8.5m.
- Reference laboratory (NYSDOH accredited lab) – autoimmune testing - $4m.
- 20% growth expected through leveraging synergies with Trinity and launch of laboratory-based tests.
- New Sjogren's test performing strongly – Nicox, Bausch and Lomb (Valeant).

Fundraising

- $115m ($110.5m net of transaction expenses) raised in April 2015 through issuance of 30 year exchangeable senior notes.
- Interest rate of 4% p.a., payable half-yearly in arrears.
- Repayment due in 2045 - a number of put and call options included allow for earlier redemption.
- Proceeds will be used for strategic acquisitions with the following characteristics:
  - Growth businesses;
  - Profitable and cash flow positive; and
  - Demonstrable synergies with existing Trinity business.

Revenue Plan (Not a Forecast)
Revenues $m - 2010-2014



Financial Information - Profit and Loss

	2010 $m	2011 $m	2012 $m	2013 $m	2014 $m
Revenue	73.4	77.9	82.5	91.2	104.9
EBITDA	17.9	19.6	21.7	22.8	23.8
Operating profit	14.0	15.8	17.2	17.9	18.0
Profit after tax	13.9	15.6	17.3	17.8	17.2
EPS (US cents)	60*	69*	77*	78	76

* 2010 – 2012 EPS adjusted for consistency to show impact of MDET (impact 4 cents)

- 2014 profit was impacted by pre-launch cardiac costs, cost of duplicate manufacturing facilities, and sales mix (Lyme and Premier instruments).
- Gross margin: 48%
- Operating margin: 17%

Financial Information – Balance Sheet

Balance sheet as at 31 March 2015	
Fixed assets	165.3
Trade and other receivables	27.9
Inventory	37.1
Cash	5.7
Current assets	70.7
Trade and other payables	(20.7)
Net current assets	50.0
Bank debt	0

- No bank debt (additional $110.5m raised in April 2015).

Take aways

- No bank debt – cash of $5.7m at 31 March 2015, with $115m fundraising completed in April 2015.
- Dividend of 22 cents per ADR (consistent with prior year).
- Cardiac tests (Fiomi) – Troponin and BNP CE Marked in 2014.
- 8 new point-of-care tests.
- FDA approval for HIV-2 claim.
- Profitable and cash generating infectious disease lab business (Brazil & China).
- 460 Premier placements in 2014, including 121 in Brazil.
- Acquisition of Immco and blood banking business strengthens position in autoimmune and infectious diseases and provides excellent synergies and growth potential.
- CLIA waiver received for syphilis rapid test – significant growth opportunity.