



POINT OF CARE | CLINICAL LABORATORY

**Your Diagnostics Partner
April 2013**



Nasdaq: TRIB

Overview

- Medical diagnostics company headquartered in Ireland.
- Quoted on NASDAQ (TRIB).
- Significant operations in the USA – direct selling force of 60; in addition to manufacturing operations in New York, Missouri and California.
- Established track record of profit growth and positive free cash flows.

Revenues



Revenue Breakdown	2010 \$m	2011 \$m	2012 \$m
Point of care	16	17	19
Infectious diseases	26	29	31
Diabetes	19	21	23
Life Science supply	12	11	10
Laboratory Business	57	61	64
Total	73	78	83

Point-of-Care: HIV Revenues

- \$19m revenues : \$12m Africa & \$7m USA (\$90m global market).
- Strong gross margins : c.55%.
- **African market**
 - President's Emergency Plan for AIDS Relief ('PEPFAR') - \$50 billion by 2013
 - WHO, World Bank, Clinton & Gates Foundations
 - Subject to a high degree of volatility quarter on quarter (>20% growth in 2012)
- **USA Market**
 - Market Size of \$58m
 - Blood \$25m (Trinity \$8m; Orasure \$10m; Chembio \$8m)
 - Saliva \$33m (Orasure \$33m)



Infectious Diseases

- **\$31m Business**
- **Strong Gross Margins**
 - >55%
- **Strong Cash Generation**
- **Broad Reagent Portfolio**
 - Leader in Lyme: US \$9m (Quest & Labcorp) (100% of Blot market)
 - Major participant in HSV: \$3m (incl. Labcorp)
 - Prominent niche player: e.g. EBV, Flu
- **Growth Drivers**
 - Strong Distribution Channels – Brazil, China
 - Instrument Placement: DSX Systems
 - Spread of Lyme Disease (90% US mkt share)
 - New Vitamin D test launched



Diabetes

- \$23m Business, 7% 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



Growth Opportunities

Key Growth Opportunities for Trinity Biotech:

- Premier (Diabetes).
- New range of point-of-care tests.
- Fiomi (Cardiac).

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 - FDA Approval – December 2011
 - Fisher and Direct salesforce
 - China (approved Q2 2013).
 - Brazil (approval expected Q2 2013)
- 202 instruments (\$4.1m) shipped in 2012
- 67 instruments shipped in Q1 2013



Premier Placements

	2012 (Units)	2013 (Units)	2014 (Units)
Menarini	71	110	160
USA	49	60	100
China	10	70	100
Turkey	30	20	20
Brazil	-	10	50
RoW	42	50	70
Total	202	320	500

New Point-of-Care Products

Lateral Flow Tests in Development

Test	Group	CE Mark	510k	CLIA	US market \$M	Global Market \$m	Main competition
Giardia	Enterics	Received	Received	N/A	10	15	Alere (8), Meridian (7)
Cryptosporidium	Enterics	Received	Received	N/A	6	10	Alere (4), Meridian (6)
C. Difficile	Enterics	May 2013	N/A	N/A	30	50	Alere (25), Meridian (25)
GDH	Enterics	June 2013	N/A	N/A	60	100	Alere (50), Meridian (50)
H. Pylori Ag	Enterics	Dec 2013	July 2014	N/A	20	30	Meridian (30)
Syphilis	STD	Received	Received	N/A	0	30	Alere (20)
Syphilis - Combo	STD	June 2014	Sept 2014	Dec 2014	0	30	Chembio (20)
HSV2	STD	Received	Received	June 2014	15	25	BioKit (25)
Legionella	Respiratory	Received	N/A	N/A	5	20	Alere (20)
S. Pneumoniae	Respiratory	Sept 2013	March 2014	N/A	5	20	Alere (20)

Fiomi Diagnostics

- Acquired Fiomi Diagnostics in March 2012 for \$13m.
- Swedish based company – advanced stage of developing a Troponin I test (marker for cardiac arrest) and BNP test (marker for heart failure).
- March 2012 (7 employees) – December 2012 (30 employees).
- Includes \$3.4m of contingent consideration –dependent on:
 - CE Marking;
 - FDA submission; and
 - FDA Approval of a Troponin I (TnI) assay.
- Costs of \$16m expected to complete the Troponin I and BNP projects – of which c.\$6.6m has been spent in 2012.

Fiomi Diagnostics - Cardiac POC Market

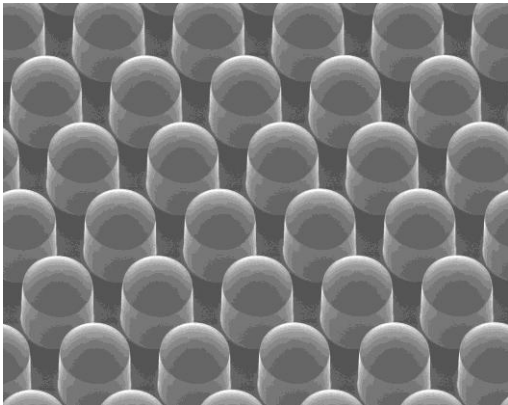
- Market Size \$900m (growing at 14% p.a.).

	Troponin I \$m	BNP \$m	Total \$m
Alere (Biosite Triage)	140	220	360
Roche (Cobas)	200	120	320
Abbott (i-STAT)	160	60	220
Total	500	400	900

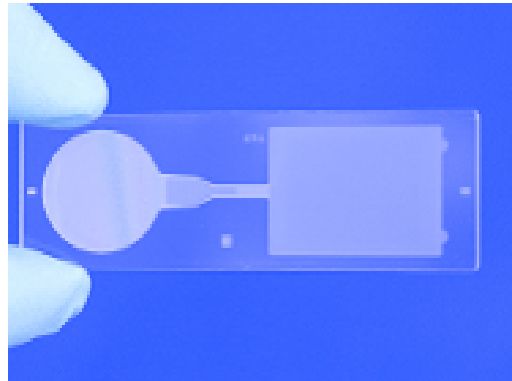
- Troponin I FDA approval guidelines tightened in 2012.
- 3 current point-of-care tests do not meet these guidelines.
- Fiomi test meets FDA guidelines – design freeze declared.
- CE trials commenced, FDA trials to commence in September 2013.

Fiomi Diagnostics - 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.



Micropillar array



Cartridge assembly



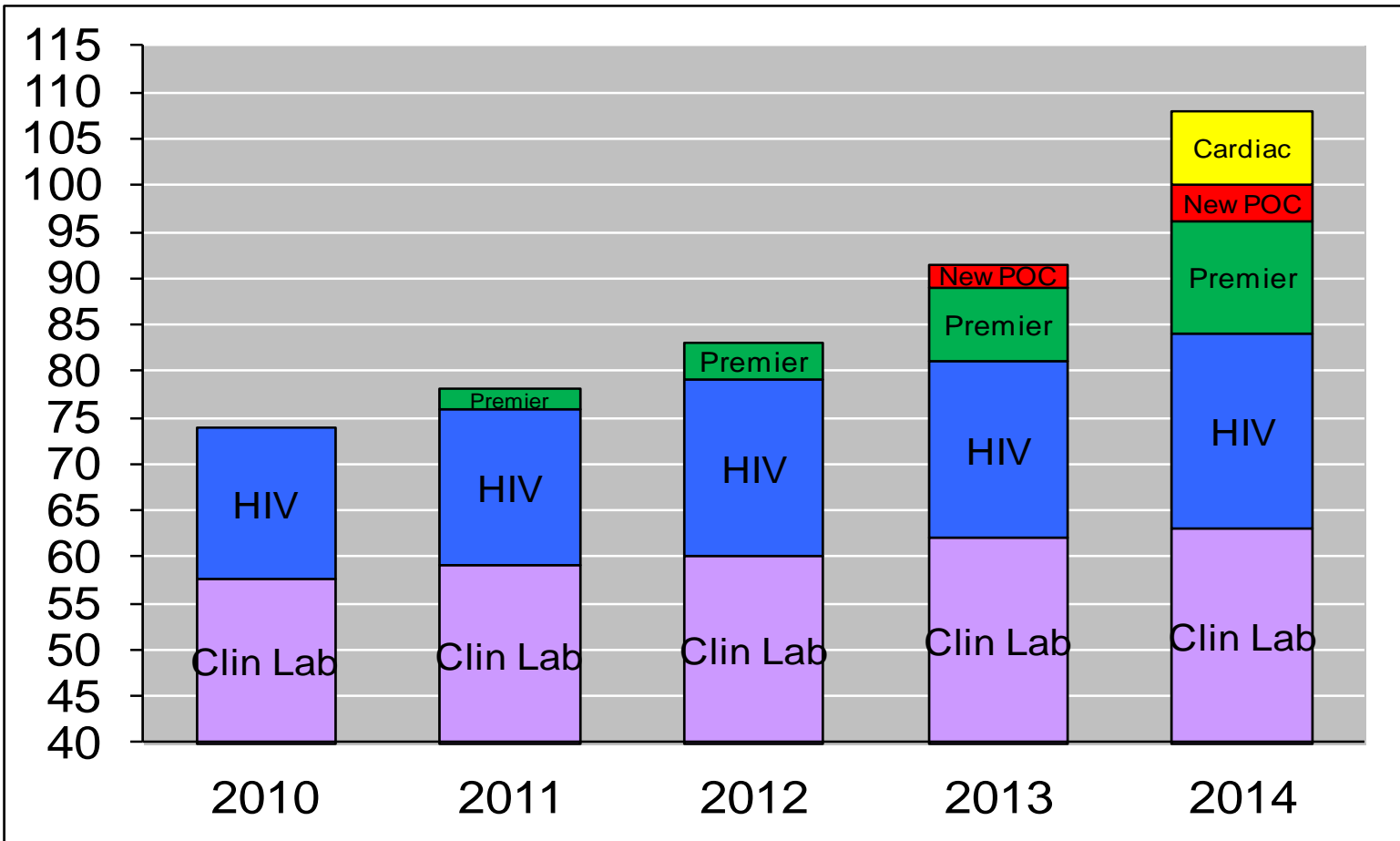
Desk-top Reader

Fiomi - Timing

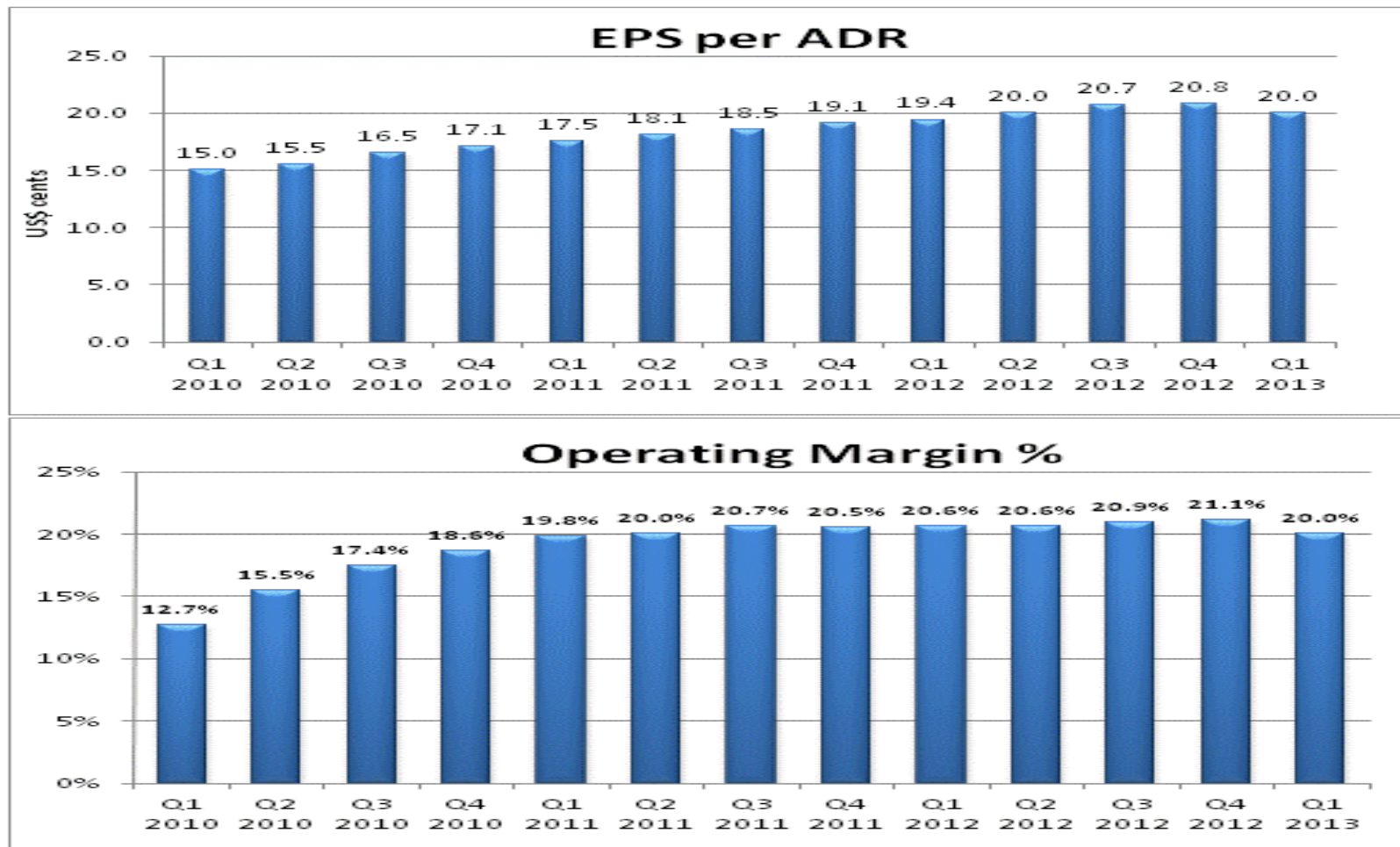
	CE Marking	FDA Submission	FDA Approval
Troponin I	Dec 2013	Mar 2014	Dec 2014
BNP	Mar 2014	June 2014	Mar 2015

- Trinity expects to obtain a significant share of the \$900m market.
- Platform technology – quantitative instrument.
- Licence from J&J for infectious diseases, autoimmune, allergy, D-dimer, veterinary and industrial.

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



Earnings Per American Depositary Receipt (ADR) & Operating Margin %



Take aways

- EPS of 81 cents per ADR in 2012 (11% increase v 2011).
- No bank debt – cash of \$73m (\$3.28 per share).
- Excluding cash – trading at approximately 15 times earnings.
- Dividend of 20 cents per ADR (33% increase on prior year).
- Share buyback – over \$11m spent to date.
- ***Point of Care***
 - Cardiac tests (Fiomi) - launching 2013/2014
 - 10 point-of-care tests – launching 2013/2014
- ***Laboratory Business***
 - Profitable and cash generating infectious disease lab business (Vitamin D, Brazil & China)
 - Premier now launched – new large growth potential – 202 placements in 2012, 320 placements in 2013 & 500 placements in 2014.