



POINT OF CARE | CLINICAL LABORATORY

**Your Diagnostics Partner**  
**March 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
<b>Point of care</b>	<b>16</b>	<b>17</b>	<b>19</b>
Infectious diseases	26	29	31
Diabetes	19	21	23
Life Science supply	12	11	10
<b>Laboratory Business</b>	<b>57</b>	<b>61</b>	<b>64</b>
<b>Total</b>	<b>73</b>	<b>78</b>	<b>83</b>

## 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 \$9m; 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
  - Brazil (approval expected Q2 2013)
  - China (approval expected Q1 2013).
- 202 instruments (\$4.1m) shipped in 2012.





## Premier Placements

	2012 (Units)	2013 (Units)	2014 (Units)
Menarini	71	120	160
USA	49	70	100
China	10	50	100
Turkey	30	20	20
Brazil	-	10	50
RoW	42	50	70
<b>Total</b>	<b>202</b>	<b>320</b>	<b>500</b>

# New Point-of-Care Products

## Lateral Flow Tests in Development

Test	Group	Status	End-user	US Market \$M	Global Market \$M	Main Competition
<b>Syphilis*</b>	STD	Awaiting CLIA Waiver	Hospital / STD Clinic	0	30	Alere (20)
<b>HSV2*</b>	STD	Awaiting CLIA Waiver	Hospital / Clinic	15	25	BioKit (25)
<b>Giardia*</b>	Enterics	510k submitted to FDA	Hospital / Clinic	10	15	Alere (8), Meridian (7)
<b>Cryptosporidium*</b>	Enterics	510k submitted to FDA	Hospital / Clinic	6	10	Alere (4), Meridian (6)
<b>C. Difficile*</b>	Enterics	510k to FDA in March '13	Hospital / Clinic	60	100	Alere (50), Meridian (50)
<b>S. Pneumoniae*</b>	Respiratory	510k to FDA in March '13	Hospital / Clinic	6	10	Alere (10)
<b>H. pylori Ag</b>	Enterics	510k to FDA in June '13	Hospital / Clinic	20	20	Meridian (20)

\* CE Marked or CE Marking imminent

## 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

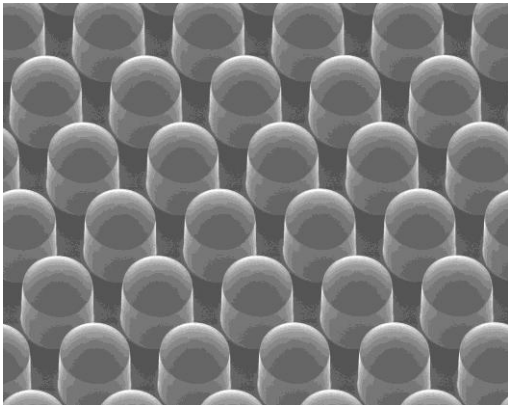
- Market Size \$900m (growing at 14% p.a.).

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

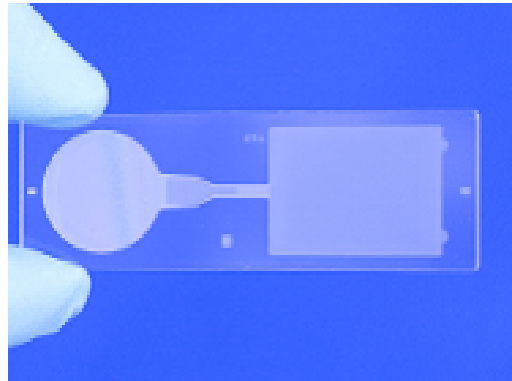
- Troponin I FDA approval guidelines tightened in 2012.
- 3 current point-of-care tests do not meet these guidelines.

## 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**



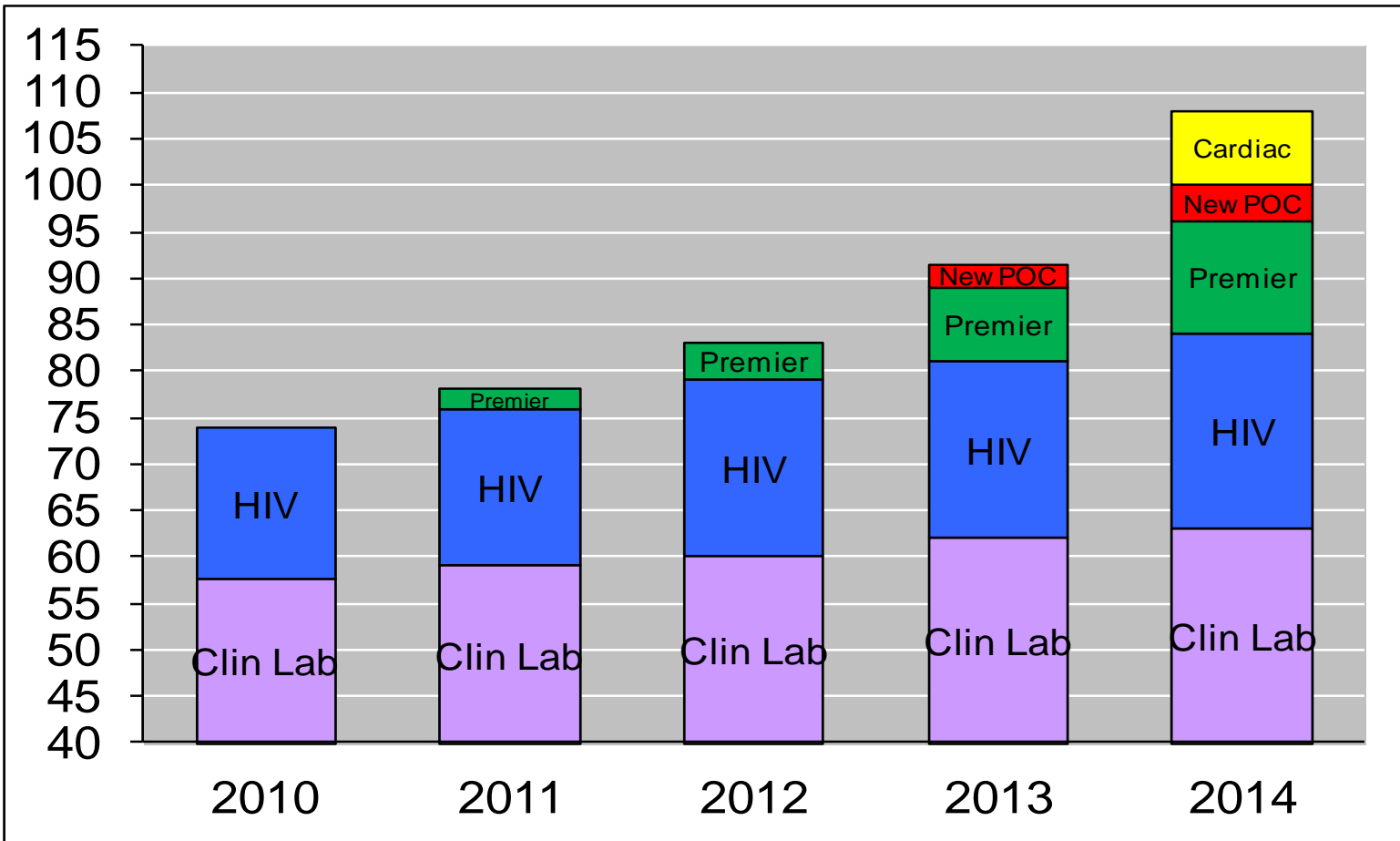
**Desk-top Reader**

## Fiomi - Timing

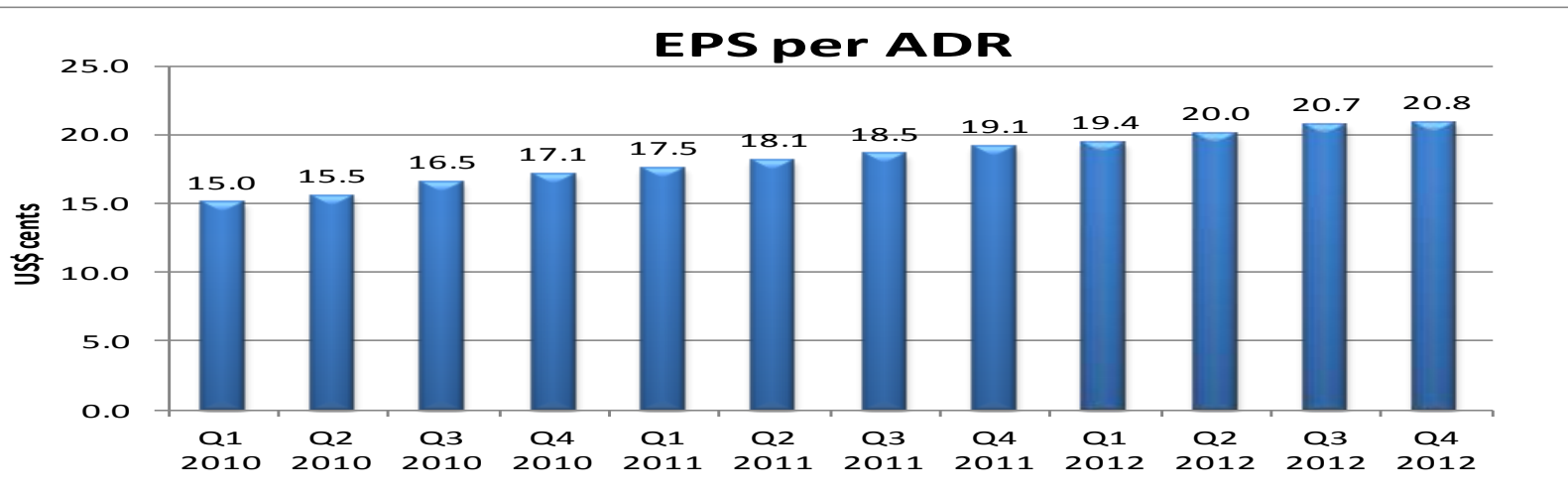
	CE Marking	FDA Submission	FDA Approval
Troponin I	Dec 2013	Mar 2014	Dec 2014
BNP	Mar 2014	June 2014	Mar 2015

- 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 \$75m (\$3.50 per share).
- Excluding cash – trading at approximately 17 times earnings.
- Dividend of 15 cents per ADR (50% increase on prior year).
- Share buyback – over \$11m spent to date.
- ***Point of Care***
  - Cardiac tests (Fiomi) - launching 2013/2014
  - 7 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.