TRINITY BIOTECH PLC
Form 6-K
May 07, 2013

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

F O R M 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 OR 15d-16

UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of May, 2013

TRINITY BIOTECH PLC

(Name of Registrant)

IDA Business Park

Bray, Co. Wicklow

Ireland

(Address of Principal Executive Office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F x **Form 40-F** ¨

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ¨

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ¨

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes ¨ **No** x

If Yes is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-

Press Release dated April 25, 2013

Contact: **Trinity Biotech plc** **Lytham Partners LLC**

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Trinity Biotech Announces Quarter 1 Results EPS of 20 cents, Premier Regulatory approval in China and 33% increase in Dividend to 20 cents.

DUBLIN, Ireland (April 25, 2013) . Trinity Biotech plc (Nasdaq: TRIB), a leading developer and manufacturer of diagnostic products for the point-of-care and clinical laboratory markets, today announced results for the quarter ended March 31, 2013.

Quarter 1 Results

Total revenues for Q1, 2013 were $20.3m which compares to $20m in Q1, 2012, an increase of 1.5%.

Point-Of-Care revenues for Q1, 2013 decreased by 7% when compared to Q1, 2012. This decrease was due to lower HIV sales in Africa. This reflects the fact that African sales fluctuate significantly quarter on quarter and that in the equivalent quarter last year these revenues were exceptionally strong. However, this was partly offset by HIV sales in the USA which increased by 5% during the period.

Clinical Laboratory revenues increased from $14.9m to $15.6m, which represents an increase of 4.4% compared to Q1, 2012. However, if Lyme sales, which have been adversely impacted by the recent cold winter, were excluded the increase would have been 8%. The main factor contributing to this increase has been the continued growth in Premier instrument and related reagent revenues.

Revenues for Q1, 2013 by key product area were as follows:

	2012 Quarter 1 US$ 000	**2013 Quarter 1 US$ 000**	**Increase/ (decrease) %**
Point-of-Care	5,121	4,765	(7.0%)
Clinical Laboratory	14,905	15,563	4.4%
Total	***20,026***	***20,328***	***1.5%***

Gross profit for Q1, 2013 amounted to $10.3m representing a gross margin of 50.9%, which compares to 51.6% for the same period in 2012. This reduction is due to lower point-of-care and Lyme sales, both of which attract higher gross margins.

Research and Development expenses remained constant at $0.9m whilst Selling, General and Administrative (SG&A) expenses fell from $5.2m in Q1, 2012 to $5.0m this quarter. This decrease was mainly due to professional fees related to the acquisition of Fiomi Diagnostics AB incurred during the comparative quarter.

Operating Profit for the quarter was $4.1m, which is broadly in line with Q1, 2012 whilst the operating margin for the quarter was 20%. Net financial income decreased by $0.1m to $0.5m this quarter.

Profit After Tax for the quarter increased from $4.1m to $4.3m (excluding the Medical Device Excise Tax) an increase of 6%. Meanwhile, EPS (excluding MDET) for Q1, 2013 increased by 3% from 19.4 cents to 20 cents.

Other Developments

Premier

The company has just received approval from the Chinese Regulatory authority, the SFDA, to commence selling its haemoglobin A1c test in China. According to the International Diabetes Federation there are 92 million diabetics in China, of which 54 million are currently undiagnosed. This number is expected to increase to 130 million by 2030. In order to address this critical issue, the Chinese Health Authorities have launched a multi-year education campaign on diabetes, whilst concurrently embarking on programs to improve the glycemic control of diabetics, increase diagnosis levels and to identify those at risk of developing diabetes. Increased haemoglobin A1c testing has been identified as the key diagnostic test for each of these programs.

The Premier is particularly well suited to the Chinese market as it uses boronate affinity technology which avoids interference from the abnormal haemoglobins that are present in a large segment of the Chinese population. This, in conjunction with its analytical and processing efficiencies, will provide Chinese laboratories with the best possible solution for A1c testing.

Trinity will distribute the Premier in China through its long-time distribution partner PGI. As has been indicated previously the company expects to achieve an initial run rate of 100 instruments per year, with further growth potential thereafter. As a first step, the company expects to ship an initial order of 20 instruments to China in Q2, 2013. The formal launch of the test has already commenced with a series of events designed to showcase the Premier to both medical and clinical laboratory professionals.

Sales of Premier instruments in other markets remained strong in Quarter 1, 2013 with a total of 67 units sold compared to 65 units in Quarter 4, 2012.

Fiomi

We have made significant advances in the development of our new cardiac point of care tests. We are able to announce that our high sensitivity Troponin I test is now demonstrating performance characteristics which fully meet the FDA guidelines for Troponin I. Consequently, we have declared design freeze on both the Troponin I assay and related instrument.

We have now commenced the clinical trials to CE mark the product in Europe and these trials will continue throughout Q2 and Q3, 2013. CE marking for the Troponin I product remains on target for Q4, 2013 and will enable us to sell the product throughout the European Union.

With regard to US FDA clinical trials, the company has engaged Dr. Fred Apple, Professor of Laboratory Medicine and Pathology and Director of Clinical Laboratories at Hennepin Medical Center, Minneapolis, Minnesota, as Principle Investigator of our US clinical trials. Dr Apple is widely acknowledged as one of the key opinion leaders in the area of Cardiac Biomarkers. We believe his assistance will be invaluable in steering the company successfully through the FDA process. US clinical trial sites are currently being recruited with the trials on target to commence in Q3, 2013 followed by FDA submission in Q1, 2014.

Meanwhile, development of the company s BNP test is progressing according to plan. The product is already exhibiting market leading performance characteristics. CE marking for this product remains on target for early 2014 with FDA approval expected in early 2015.

Annual Dividend

The company is proposing a dividend of 20 cents per ADR, representing an increase of 33% on the dividend paid in 2012. The payment of this dividend is subject to shareholder approval, which will be sought at the company s forthcoming AGM to be held on May 24, 2013. Subject to this approval being granted, the record date will be June 10, 2013 and payment will follow approximately 3 weeks later.

Comments

Commenting on the results, Kevin Tansley, Chief Financial Officer, said Revenues this quarter increased by 1.5%. However, if the impact of Lyme sales, which were adversely affected by the recent cold winter, and African HIV sales, which tend to vary significantly quarter on quarter were excluded, the growth rate would have been 8%. Meanwhile, profit after tax grew by 6% to over $4.3m for the quarter (excluding the impact of the new Medical Device Excise Tax).

Ronan O Caoimh, CEO, stated that As well as continuing revenue and earnings growth this quarter the company achieved some important key milestones. Approval of our haemoglobin A1c test in China is a very significant event for the company. With over 90 million diabetics, China represents a huge and growing market for A1c testing. The competitive advantages of interference free and high speed testing make our test ideally suited for the Chinese laboratory market. We are thus very confident that in China we will replicate the success the Premier has had in other markets and will quickly reach a run rate of at least 100 instruments per year.

Meanwhile, the development of our new cardiac tests continues to make excellent progress. Our Troponin I test, which has reached design freeze stage, we believe now meets the new stringent FDA guidelines for Troponin testing. As a result we have now commenced the clinical trials to CE mark the product with FDA clinical trials due to commence later this year. Similarly, our BNP test for heart failure is also progressing very well and remains on target for CE marking in early 2014 and FDA approval in 2015.

Finally, we are announcing an annual dividend of 20 cents this year. This represents an increase of 33% over last year. This is just the third year of our dividend program and in that time the amount of the dividend has doubled in size.

Litigation Reform Act of 1995. Investors are cautioned that such forward-looking statements involve risks and uncertainties including, but not limited to, the results of research and development efforts, the effect of regulation by the United States Food and Drug Administration and other agencies, the impact of competitive products, product development commercialisation and technological difficulties, and other risks detailed in the Company s periodic reports filed with the Securities and Exchange Commission.

Trinity Biotech develops, acquires, manufactures and markets diagnostic systems, including both reagents and instrumentation, for the point-of-care and clinical laboratory segments of the diagnostic market. The products are used to detect infectious diseases and to quantify the level of Haemoglobin A1c and other chemistry parameters in serum, plasma and whole blood. Trinity Biotech sells direct in the United States, Germany, France and the U.K. and through a network of international distributors and strategic partners in over 75 countries worldwide. For further information please see the Company s website: www.trinitybiotech.com

Trinity Biotech plc

Consolidated Income Statements

(US$000 s except share data)	**Three Months Ended March 31, 2013 (unaudited)**	**Three Months Ended March 31, 2012 (unaudited)**
Revenues	**20,328**	**20,026**
Cost of sales	(9,990)	(9,683)
Gross profit	**10,338**	**10,343**
Gross profit %	*50.9%*	*51.6%*
Other operating income	110	175
Research & development expenses	(855)	(845)
Selling, general and administrative expenses	(5,033)	(5,204)
Indirect share based payments	(498)	(337)
Operating profit	**4,062**	**4,132**
Financial income	477	546
Financial expenses	(26)	(1)
Net financing income	451	545
Profit before tax	**4,513**	**4,677**
Income tax expense	(174)	(567)
Profit for the period before MDET	**4,339**	**4,110**
Medical devices excise tax (MDET)	(171)	
Profit for the period after MDET	**4,168**	**4,110**
Earnings per ADR (US cents)	19.3	19.4
Diluted earnings per ADR (US cents)	18.3	18.6
Earnings per ADR excluding MDET (US cents)	20.0	19.4
Diluted earnings per ADR excluding MDET (US cents)	19.0	18.6
Weighted average no. of ADRs used in computing basic earnings per ADR	21,631,713	21,217,683
Weighted average no. of ADRs used in computing diluted earnings per ADR	22,809,958	22,154,641

The above financial statements have been prepared in accordance with the principles of International Financial Reporting Standards and the Company s accounting policies but do not constitute an interim financial report as defined in IAS 34 (Interim Financial Reporting).

Trinity Biotech plc

Consolidated Balance Sheets

	March 31, 2013 US$ 000 (unaudited)	Dec 31, 2012 US$ 000 (audited)
ASSETS		
Non-current assets		
Property, plant and equipment	9,331	8,883
Goodwill and intangible assets	76,748	73,046
Deferred tax assets	4,533	4,073
Other assets	945	908
Total non-current assets	91,557	86,910
Current assets		
Inventories	23,110	20,757
Trade and other receivables	15,299	14,457
Income tax receivable	322	336
Cash and cash equivalents	73,095	74,947
Total current assets	111,826	110,497
TOTAL ASSETS	203,383	197,407
EQUITY AND LIABILITIES		
Equity attributable to the equity holders of the parent		
Share capital	1,143	1,134
Share premium	5,449	5,138
Accumulated surplus	163,886	158,973
Other reserves	4,128	4,135
Total equity	174,606	169,380
Current liabilities		
Income tax payable	1,261	1,092
Trade and other payables	12,955	11,824
Provisions	50	50
Total current liabilities	14,266	13,966
Non-current liabilities		
Other payables	3,344	4,318
Deferred tax liabilities	11,167	10,743
Total non-current liabilities	14,511	14,061
TOTAL LIABILITIES	28,777	28,027
TOTAL EQUITY AND LIABILITIES	203,383	197,407

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Trinity Biotech plc

Consolidated Statement of Cash Flows

(US$000 s)	**Three Months Ended March 31, 2013**	**Three Months Ended March 31, 2012**
	(unaudited)	**(unaudited)**
Cash and cash equivalents at beginning of period	**74,947**	**71,085**
Operating cash flows before changes in working capital	5,177	5,115
Changes in working capital	(2,551)	(1,821)
Cash generated from operations	2,626	3,294
Net Interest and Income taxes received	432	475
Capital Expenditure & Financing (net)	(4,910)	(2,387)
Free cash flow	(1,852)	1,382
Cash paid to acquire Phoenix Bio-tech		(333)
Cash paid to acquire Fiomi Diagnostics		(5,624)
Repurchase of own company shares		(1,011)
Cash and cash equivalents at end of period	**73,095**	**65,499**

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TRINITY BIOTECH PLC
(Registrant)

By: /s/ Kevin Tansley
Kevin Tansley
Chief Financial Officer

Date: May 7, 2013.