

TRINITY BIOTECH PLC  
Form 6-K  
April 30, 2014

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 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 April, 2014**

**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  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

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 29, 2014

Contact: **Trinity Biotech plc**

Kevin Tansley  
(353)-1-2769800

E-mail: [kevin.tansley@trinitybiotech.com](mailto:kevin.tansley@trinitybiotech.com)

**Lytham Partners LLC**

Joe Diaz, Joe Dorame & Robert Blum  
602-889-9700

### **Trinity Biotech Announces Quarter 1 Results**

**Revenues up 23%, Operating profit up 16%**

**Increase in Dividend to 22 cents**

**DUBLIN, Ireland (April 29, 2014)** . 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, 2014.

#### ***Quarter 1 Results***

Total revenues for Q1, 2014 were \$25.0m which compares to \$20.3m in Q1, 2013, an increase of 23%.

Point-Of-Care revenues for Q1, 2014 decreased by 5% when compared to Q1, 2013. HIV sales in the USA were slightly up compared with the comparative period, thus arresting the decline in recent quarters due to the lower availability of federal funding. This reflects the initial impact of Trinity's recent FDA approval for a claim for HIV-2 on its Uni-gold product. Meanwhile, sales in Africa were lower, reflecting the fact that African sales tend to fluctuate significantly quarter on quarter.

Clinical Laboratory revenues increased from \$15.6m to \$20.5m, which represents an increase of nearly 32% compared to Q1, 2013. The main factors contributing to this increase have been the continued growth in Premier instrument and related reagent revenues plus the impact of the Immco and blood bank screening acquisitions which were undertaken during 2013, though this was partly offset by lower Fitzgerald revenues.

Revenues for Q1, 2014 by key product area were as follows:

	<b>2013 Quarter 1 US\$ 000</b>	<b>2014 Quarter 1 US\$ 000</b>	<b>Increase/ (decrease) %</b>
Point-of-Care	4,765	4,506	-5.4%
Clinical Laboratory	15,563	20,519	31.8%
<b>Total</b>	<b>20,328</b>	<b>25,025</b>	<b>23.1%</b>

Gross profit for Q1, 2014 amounted to \$12.2m, which compares to \$10.2m for the same period in 2013. Gross margin for the quarter was 48.6%. This represents a reduction from 50% in Q1, 2013, which was mainly due to the impact of

higher Premier instrument sales this quarter.

Research and Development expenses increased from \$0.9m to \$1.0m, whilst Selling, General and Administrative (SG&A) expenses also increased from \$5.0m in Q1, 2013 to \$6.3m this quarter. These increases were mainly due to the impact of the acquisitions undertaken in 2013 and also initial sales and marketing costs in relation to launching the first test on the Meritas platform.

Operating profit for the quarter was \$4.5m which represents an increase of 16% compared to Q1, 2013. Operating margin for the quarter was 18%. Profit before tax for the quarter increased from \$4.3m to \$4.5m, whilst profit after tax increased by 6% to \$4.4m. Meanwhile, EPS for Q1, 2014 increased from 19.3 cents to 19.6 cents. EBITDA and before share option expense for the quarter increased from \$5.2m to \$6m an increase of 16%.

The tax charge for the quarter was \$0.1m which represents an effective tax rate of 2.5%. This unusually low rate has been driven by the availability of R&D tax credits in both Ireland and North America, in addition to the normal low rate of corporation tax rate in Ireland.

Notwithstanding that Q1 tends to be our weakest quarter due to seasonal factors (i.e. very low lyme sales), 23% growth in revenues represented a very strong performance. However, overall profitability this quarter was impacted by a number of factors:

**Higher instrument sales:-** This quarter saw the highest number of Premier instruments shipped in a single quarter instrument sales on average earn a lower gross margin.

**Acquisitions undertaken in 2013:-** Whilst Immco was profitable during the period, the operating losses associated with the blood banking acquisition have more than offset this. These losses are due to the carrying costs associated with two manufacturing plants in the UK and had been anticipated at the time of acquisition. Manufacturing is currently being transferred from these two plants to Trinity's existing plants in Bray, Ireland and Jamestown, New York. Following the completion of the transfer of manufacturing in early Q3, 2014 the two plants in the UK will be closed, resulting in considerable cost savings.

**Meritas costs:-** This quarter we are seeing the initial costs associated with launching our Meritas product range. We are currently in the process of building a sales and technical organisation to support this product range with a consequent increase in costs. To date we have recruited a number of sales and technical specialists and have incurred significant branding and marketing costs. Given that CE marking for the first Meritas product, Troponin I, has only been received recently this has created a temporary imbalance as these costs are not yet being offset by associated revenues. As revenues increase in the quarters ahead, this imbalance will be addressed resulting in improved profitability.

## **Other Developments**

### ***Meritas (Cardiac)***

During the quarter, CE marking was obtained for the company's new high sensitivity Troponin I test which is being marketed under the Meritas name. As well as representing EU approval for the product, the associated trials demonstrated that it is the only point-of-care Troponin test capable of meeting all of the guidelines stipulated by the world's leading cardiac organisations for diagnosis of heart attacks. Following the granting of CE marking, clinical trials for FDA approval for the Troponin test commenced. These trials, which are being carried out at six trial sites in the USA, are progressing well and we remain on target to submit the results to the FDA in late 2014. The product has already been launched in Europe where distributors have been appointed in each of the main markets with the exception of Scandinavia and the UK where Trinity will be selling the product using its own direct sales forces.

During the quarter, significant progress was also made with regard to finalising the development of the company's BNP test for heart failure on the same platform. CE marking for this product is expected to be received by the end of Q2, 2014. This will be followed soon thereafter by the commencement of FDA clinical trials with submission expected in Q4, 2014 and FDA approval anticipated in the first half of 2015.

Meanwhile, development has commenced on the third test on this platform, D-dimer. This product will be launched in 2016 and will be followed by a range of other tests suitable for the point-of-care/emergency room environment.

### ***Premier***

During the quarter the Company sold 101 Premier instruments, which compares to 67 instruments sold in Q1, 2013 an increase of 51%. This represents the highest number of instruments sold in a single quarter since the product was launched and included the first 21 instruments to be sold in Brazil following its approval by the Brazilian regulatory authority, Anvisa. We were very pleased with such strong instrument sales so soon after approval and also with the very positive sales pipeline that is already in place for future quarters in Brazil. In addition, a significant number of instruments were sold in China where the instrument continues to gain traction. In 2014, the Company is targeting worldwide sales in excess of 460 Premier instruments.

### ***Annual Dividend***

The company is proposing a dividend of 22 cents per ADR, representing an increase of 10% on the dividend paid in 2013. The payment of this dividend is subject to shareholder approval, which will be sought at the company's forthcoming AGM to be held on June 6, 2014. Subject to this approval being granted, the record date will be June 10, 2014 and payment will follow approximately 3 weeks later.

### **Comments**

Commenting on the results, Kevin Tansley, Chief Financial Officer, said "Operating profit increased by 16% this quarter, whilst overall profit increased from \$4.2m to over \$4.4m resulting in an EPS of 19.6 cents. These results were achieved notwithstanding the additional operating costs associated with the blood banking acquisition prior to the transfer of manufacturing operations from the UK to other existing Trinity plants in early quarter 3, 2014. In addition, we have started to incur costs associated with launching the first of our Meritas products, Troponin, though given the recent launch date these have yet to be matched by equivalent revenues. With the closure of the UK manufacturing operations and increased revenues, profitability can be expected to improve further as the year progresses.

Ronan O' Caoimh, CEO, stated that "During quarter 1 we achieved a key milestone with the CE marking of our new high sensitivity point-of-care Troponin product. We are also very happy to announce that we have commenced FDA trials for this product at six trial sites located in the USA. To date, these trials have been progressing well and we are on target to file our submission with the FDA late in 2014. This will soon be followed by a similar submission for our BNP test which is nearing completion and which will commence its CE marking trials shortly.

This quarter was very successful for sales of our diabetes analyzer, Premier. With 101 instruments sold this quarter, this represents the highest number of these instruments sold in any quarter since its launch and is a 51% increase over the same period last year. We are delighted that our direct sales force in Brazil sold 21 Premier instruments this quarter, immediately following registration. With over 12m diabetics, Brazil now has the fourth highest number of sufferers of diabetes in the world. Consequently, we have identified Brazil as a key market for the Premier instrument and one in which we expect to deliver significant growth going forward. We have also commenced the registration process for our infectious diseases product range in Brazil, approval for which is expected to be received in 2015.

Finally, we are proposing an annual dividend of 22 cents this year. This represents an increase of 10% over last year. This is just the fourth year of our dividend program and we have already established a strong track record of dividend growth.

*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](http://www.trinitybiotech.com)

**Trinity Biotech plc**  
**Consolidated Income Statements**

	<b>Three Months Ended March 31, 2014</b>	<b>Three Months Ended March 31, 2013</b>
	<b>(unaudited)</b>	<b>(unaudited)</b>
<i>(US\$000 s except share data)</i>		
<b>Revenues</b>	<b>25,025</b>	<b>20,328</b>
Cost of sales	(12,864)	(10,161)
<b>Gross profit</b>	<b>12,161</b>	<b>10,167</b>
Gross profit %	48.6%	50.0%
Other operating income	149	110
Research & development expenses	(1,037)	(855)
Selling, general and administrative expenses	(6,314)	(5,033)
Indirect share based payments	(455)	(498)
<b>Operating profit</b>	<b>4,504</b>	<b>3,891</b>
Financial income	43	477
Financial expenses	(20)	(26)
<b>Net financing income</b>	<b>23</b>	<b>451</b>
<b>Profit before tax</b>	<b>4,527</b>	<b>4,342</b>
Income tax expense	(114)	(174)
<b>Profit for the period</b>	<b>4,413</b>	<b>4,168</b>
Earnings per ADR (US cents)	19.6	19.3
Diluted earnings per ADR (US cents)	18.2	18.3
Weighted average no. of ADRs used in computing basic earnings per ADR	22,465,202	21,631,713
Weighted average no. of ADRs used in computing diluted earnings per ADR	24,209,680	22,809,958

*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, 2014	Dec 31, 2013
	US\$ 000	US\$ 000
	(unaudited)	(audited)
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, plant and equipment	13,841	12,991
Goodwill and intangible assets	133,881	128,547
Deferred tax assets	7,570	7,044
Other assets	1,131	1,162
<b>Total non-current assets</b>	<b>156,423</b>	<b>149,744</b>
<b>Current assets</b>		
Inventories	30,864	29,670
Trade and other receivables	24,130	24,268
Income tax receivable	493	487
Cash and cash equivalents	17,008	22,317
<b>Total current assets</b>	<b>72,495</b>	<b>76,742</b>
<b>TOTAL ASSETS</b>	<b>228,918</b>	<b>226,486</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Equity attributable to the equity holders of the parent</b>		
Share capital	1,187	1,170
Share premium	9,731	8,842
Accumulated surplus	174,023	168,670
Other reserves	4,073	4,329
<b>Total equity</b>	<b>189,014</b>	<b>183,011</b>
<b>Current liabilities</b>		
Income tax payable	998	770
Trade and other payables	15,679	20,131
Provisions	75	75
<b>Total current liabilities</b>	<b>16,752</b>	<b>20,976</b>
<b>Non-current liabilities</b>		
Other payables	4,634	4,596

Deferred tax liabilities	18,518	17,903
<b>Total non-current liabilities</b>	23,152	22,499
<b>TOTAL LIABILITIES</b>	39,904	43,475
<b>TOTAL EQUITY AND LIABILITIES</b>	228,918	226,486

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## Trinity Biotech plc

## Consolidated Statement of Cash Flows

	Three Months Ended March 31, 2014	Three Months Ended March 31, 2013
	(unaudited)	(unaudited)
<i>(US\$000 s)</i>		
<b>Cash and cash equivalents at beginning of period</b>	<b>22,317</b>	<b>74,947</b>
Operating cash flows before changes in working capital	4,993	5,177
Changes in working capital	(4,212)	(2,551)
Cash generated from operations	781	2,626
Net Interest and Income taxes received	2	432
Capital Expenditure & Financing (net)	(5,042)	(4,910)
Free cash flow	(4,259)	(1,852)
Deferred consideration	(1,050)	
<b>Cash and cash equivalents at end of period</b>	<b>17,008</b>	<b>73,095</b>

*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).*

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: April 29, 2014.