

TRINITY BIOTECH PLC  
Form 6-K  
May 01, 2015

**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, 2015**

**TRINITY BIOTECH PLC**

**(Name of Registrant)**

**IDA Business Park**

**Bray, Co. Wicklow**

**Ireland**

**(Address of Principal Executive Office)**

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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 30, 2015

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**Lytham Partners LLC**

Joe Diaz, Joe Dorame & Robert Blum  
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**Trinity Biotech Announces Quarter 1 Results EPS 17.4 cents**

**Dividend of 22 cents**

**DUBLIN, Ireland (April 30, 2015)** . 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, 2015.

***Quarter 1 Results***

Total revenues for Q1, 2015 were \$25.2m, an increase of \$0.2m when compared with Q1, 2014. However, revenues this quarter were particularly impacted by foreign exchange movements due to the strengthening of the US dollar against a range of currencies. Excluding this currency effect, revenues would have increased to \$26.4m, representing an increase of 6%.

Point-Of-Care revenues for Q1, 2015 increased by 2% (or 4.4% on a constant currency basis) when compared to Q1, 2014. This increase is due to the impact of the initial sales of the newly CLIA waived Syphilis rapid test.

Clinical Laboratory revenues increased from \$20.5m to \$20.7m, which represents an increase of approximately 1% compared to Q1, 2014. However, on a constant currency basis Q1, 2015 revenues were \$21.7m an increase of 6%. The principal factors contributing to this increase were the continued growth in Premier revenues due to higher reagent pull-through, in addition to higher autoimmune revenues from Immco.

Revenues for Q1, 2015 by key product area were as follows:

|                     | 2014          |               | 2015          |                             | Increase/<br>(decrease)<br>% |
|---------------------|---------------|---------------|---------------|-----------------------------|------------------------------|
|                     | Quarter 1     |               | Quarter 1     |                             |                              |
|                     | US\$ 000      | US\$ 000      | US\$ 000      | FX<br>adjusted*<br>US\$ 000 |                              |
| Point-of-Care       | 4,506         | 4,585         | 4,702         | 4.4%                        |                              |
| Clinical Laboratory | 20,519        | 20,655        | 21,742        | 6.0%                        |                              |
| <b>Total</b>        | <b>25,025</b> | <b>25,240</b> | <b>26,444</b> | <b>5.7%</b>                 |                              |

\* *quarter 1, 2015 revenues have been recalculated on a constant currency basis using the exchange rates prevailing in Q1, 2014*

Whilst exchange rate movements have adversely impacted revenues this quarter, they have had a favourable impact on the company's cost base. The company has an effective natural currency hedge between revenues and costs, thus the exchange rate movements this quarter had no impact on the company's overall profit. In summary, the extent to which revenues and gross profit have been adversely impacted by the stronger dollar was offset by lower foreign currency denominated SG&A expenses.

The gross profit for Q1, 2015 amounted to \$12.1m, which equates to a gross margin of 47.9%. This represents a slight reduction from 48.6% in Q1, 2014, which is partly explained by the impact of the abovementioned currency movements.

Research and Development expenses were consistent with Q1, 2014 at \$1.0m, whilst Selling, General and Administrative (SG&A) expenses also remained largely in line with Q1, 2014 at \$6.3m. The latter includes the favourable impact of the stronger dollar, offset by increased sales and marketing costs, mainly relating to Meritas.

Operating profit for the quarter was \$4.3m, compared to \$4.5m in Q1, 2014. Operating margin for the quarter was 17.2%. Profit before tax for the quarter was \$4.3m, whilst profit after tax was \$4.0m. Meanwhile, EPS for Q1, 2015 was 17.4 cents. However, this quarter we incurred over \$0.6m of SG&A costs related to Meritas, against which we have no matching revenues. Excluding such costs would have resulted in after tax profits of approximately \$4.6m or over 20 cents per ADR.

EBITDA and before share option expense for the quarter increased from \$6.0m to \$6.2m – an increase of over 3%.

The tax charge for the quarter was \$0.3m which represents an effective tax rate of 7%. This highly competitive rate has been driven by the low rate of corporation tax in Ireland and the availability of R&D tax credits in both Ireland and North America.

## **Other Developments**

### ***Cardiac Update***

In February 2015, the company announced that, after a brief cessation, it had recommenced US clinical trials on its Troponin I point-of-care product. The clinical trial is running at 12, geographically diverse, trial sites across the USA and is currently recruiting just under 70 patients per week. Furthermore, the actual rate of myocardial infarctions is tracking slightly higher than expected. Consequently, the project remains on course to have data collection, subsequent adjudication and statistical analysis all completed during the month of July with FDA submission planned for August, 2015. The product continues to demonstrate the excellent clinical performance demonstrated in our European CE marking trials and in the independent clinical evaluation carried out at Hennepin County Medical Center, Minneapolis and published at AACC in July, 2014. Furthermore, European evaluations are well underway along with product registrations in a number of countries including both China and Brazil.

In relation to Meritas BNP, the company expects USA clinical trials to be completed in September, 2015 with FDA submission following immediately thereafter. Finally, data from an independent clinical evaluation of the Meritas BNP product, carried out by Dr. Apple at Hennepin County, has been accepted for publication at the AACC meeting in Atlanta on July 26, 2015. This data indicates excellent clinical performance characteristics for Meritas BNP.

### ***Appointment of new Chief Scientific Officer***

Trinity Biotech is pleased to announce the appointment of Eric Brouwer, PhD, as Chief Scientific Officer (CSO), and Vice President Cardiac. Previously, Dr Brouwer led product development at Abbott Point-of-Care. He brings extensive leadership experience in creating, developing and launching FDA approved products for the point-of-care in vitro diagnostics market. At Abbott, he was a member of the Scientific Governing Board and was the recipient of the Abbott Chairman's Award (2007) for the FDA 510(k) waiver clearance of a point-of-care Basic Metabolic test panel. As CSO and VP Cardiac, Dr Brouwer will lead product development in our Cardiac Marker and Infectious Diseases Point-of-Care businesses.

Dr Jim Walsh, who previously held the positions of both Business Development Director and CSO, will now focus on business development with an emphasis on the identification and execution of suitable acquisition targets.

### ***Fundraising and Shelf Registration***

The company raised \$115m in April from the issuance of 4% exchangeable senior notes repayable in 2045. However, due to the inclusion of a series of put and call options, earlier redemption is possible. The initial offering of \$100m included a 30-day option to purchase an additional \$15m of the notes, an option that was fully exercised. The net proceeds from the offering for Trinity amounted to \$110.5m after deducting the associated costs of the transaction. The Company's intention is that these proceeds will be used for future acquisitions.

On April 22, the company filed a \$200m shelf registration with the SEC. This in no way represents an intention to issue equity at this time, but rather reflects the implementation of a new policy to maintain a live shelf registration at all times.

### ***Annual Dividend***

The company is proposing a dividend of 22 cents per ADR (5.5 cents per A ordinary share), which is consistent with the dividend paid in 2014. 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 5, 2015. Subject to this approval being granted, the record date will be June 9, 2015 and payment will follow approximately 3 weeks later.

### **Comments**

Commenting on the results, Kevin Tansley, Chief Financial Officer, said Revenues increased by \$0.2m to \$25.2m this quarter. However, taking into account exchange rate movements this represents an increase of nearly 6% on a constant currency basis. This growth was largely attributable to our very successful Premier offering and higher Immco autoimmune sales. Profit for the period amounted to \$4m which represent an EPS of 17.4 cents whilst EBITDA and before share option expense increased to \$6.2m.

Ronan O Caoimh, CEO, stated that During quarter 1, the business performed well, effectively achieving growth of 6%, with Premier and Immco both performing strongly. We are also very excited with the rapid syphilis market opportunity in the USA. Whilst sales to date have been modest, we are delighted with the enormous level of interest the product has generated, with virtually every state and major city health department in the USA having expressed an interest in using the test. This augurs very well for the future of this product, though given the nature of government spending, it will take some time before we achieve a significant level of sales.

We are also delighted with the progress in our Troponin I clinical trials. The product continues to demonstrate excellent clinical performance and we expect to submit the trial data to the FDA in August of this year. In addition, the registration process is well underway in a number of other countries, such as China and Brazil, both of which represent very significant market opportunities for Trinity.

In April, the company completed a significant fundraising in the form of 30 year 4% exchangeable senior notes, which yielded \$110.5m, net of expenses. The company intends to use these funds to make strategic acquisitions. The company has a history of identifying and effectively integrating high quality acquisitions. We will focus on acquisitions which will be earnings enhancing and cash flow positive, have distinct operational synergies with our existing business, whilst at the same time demonstrating strong growth potential.

Today we are also proposing an annual dividend of 22 cents per ADR. This is consistent with the dividend declared in 2014.

Finally, I would like to welcome Dr. Eric Brouwer to the company in the role of Chief Scientific Officer and VP Cardiac. Eric has a vast amount of experience, particularly in the area of developing and launching cardiac products and will be a most valuable addition to our team and I have no doubt that he will make a very significant contribution to the launch of our new Meritas range of products.

*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**

|   | Three Months<br>Ended<br>March 31,<br>2015 | Three Months<br>Ended<br>March 31,<br>2014 |
|---|--|--|
|   | (unaudited)                                | (unaudited)                                |
| <i>(US\$000 s except share data)</i>                                    |  |  |
| <b>Revenues</b>   | <b>25,240</b>                              | <b>25,025</b>                              |
| Cost of sales   | (13,140)                                   | (12,864)                                   |
| <b>Gross profit</b>   | <b>12,100</b>                              | <b>12,161</b>                              |
| Gross profit %  | 47.9%                                      | 48.6%                                      |
| Other operating income  | 78   | 149  |
| Research & development expenses   | (998)                                      | (1,037)                                    |
| Selling, general and administrative expenses                            | (6,287)                                    | (6,314)                                    |
| Indirect share based payments   | (558)                                      | (455)                                      |
| <b>Operating profit</b>   | <b>4,335</b>                               | <b>4,504</b>                               |
| Financial income  | 1  | 43   |
| Financial expenses  | (24)                                       | (20)                                       |
| <b>Net financing (expense)/income</b>                                   | <b>(23)</b>                                | <b>23</b>                                  |
| <b>Profit before tax</b>  | <b>4,312</b>                               | <b>4,527</b>                               |
| Income tax expense  | (304)                                      | (114)                                      |
| <b>Profit for the period</b>  | <b>4,008</b>                               | <b>4,413</b>                               |
| Earnings per ADR (US cents)   | 17.4                                       | 19.6                                       |
| Diluted earnings per ADR (US cents)                                     | 17.0                                       | 18.2                                       |
| Weighted average no. of ADRs used in computing basic earnings per ADR   | 22,985,234                                 | 22,465,202                                 |
| Weighted average no. of ADRs used in computing diluted earnings per ADR | 23,604,244                                 | 24,209,680                                 |

*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,<br>2015<br>US\$ 000<br>(unaudited) | Dec 31,<br>2014<br>US\$ 000<br>(unaudited) |
|--|--|--|
| <b>ASSETS</b>  |  |  |
| <b>Non-current assets</b>                                      |  |  |
| Property, plant and equipment                                  | 17,760                                       | 17,877                                     |
| Goodwill and intangible assets                                 | 147,568                                      | 145,024                                    |
| Deferred tax assets  | 9,528  | 9,798                                      |
| Other assets   | 1,249  | 1,194                                      |
| <b>Total non-current assets</b>                                | <b>176,105</b>                               | <b>173,893</b>                             |
| <b>Current assets</b>  |  |  |
| Inventories  | 37,064                                       | 33,516                                     |
| Trade and other receivables                                    | 27,640                                       | 25,976                                     |
| Income tax receivable  | 221  | 351  |
| Cash and cash equivalents                                      | 5,745  | 9,102                                      |
| <b>Total current assets</b>                                    | <b>70,670</b>                                | <b>68,945</b>                              |
| <b>TOTAL ASSETS</b>  | <b>246,775</b>                               | <b>242,838</b>                             |
| <b>EQUITY AND LIABILITIES</b>                                  |  |  |
| <b>Equity attributable to the equity holders of the parent</b> |  |  |
| Share capital  | 1,215  | 1,204                                      |
| Share premium  | 14,393                                       | 12,422                                     |
| Accumulated surplus  | 188,094                                      | 183,375                                    |
| Other reserves   | (2,463)                                      | (29)                                       |
| <b>Total equity</b>  | <b>201,239</b>                               | <b>196,972</b>                             |
| <b>Current liabilities</b>                                     |  |  |
| Income tax payable   | 467  | 785  |
| Trade and other payables                                       | 20,116                                       | 21,197                                     |
| Provisions   | 75   | 75   |
| <b>Total current liabilities</b>                               | <b>20,658</b>                                | <b>22,057</b>                              |
| <b>Non-current liabilities</b>                                 |  |  |
| Other payables   | 3,205  | 2,370                                      |



|                                     |                |                |
|-------------------------------------|----------------|----------------|
| Deferred tax liabilities            | 21,673         | 21,439         |
| Total non-current liabilities       | 24,878         | 23,809         |
| <b>TOTAL LIABILITIES</b>            | <b>45,536</b>  | <b>45,866</b>  |
| <b>TOTAL EQUITY AND LIABILITIES</b> | <b>246,775</b> | <b>242,838</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).*

## Trinity Biotech plc

## Consolidated Statement of Cash Flows

|   | Three Months<br>Ended<br>March 31,<br>2015 | Three Months<br>Ended<br>March 31,<br>2014 |
|---|--|--|
|   | (unaudited)                                | (unaudited)                                |
| <i>(US\$000 s)</i>                                      |  |  |
| <b>Cash and cash equivalents at beginning of period</b> | <b>9,102</b>                               | <b>22,317</b>                              |
| Operating cash flows before changes in working capital  | 6,298                                      | 4,993                                      |
| Changes in working capital                              | (4,322)                                    | (4,212)                                    |
| Cash generated from operations                          | 1,976                                      | 781  |
| Net Interest and Income taxes (paid)/received           | (108)                                      | 2  |
| Capital Expenditure & Financing (net)                   | (4,113)                                    | (5,042)                                    |
| Free cash flow  | (2,245)                                    | (4,259)                                    |
| Payment of HIV-2 licence fee                            | (1,112)                                    |  |
| Deferred consideration paid                             |  | (1,050)                                    |
| <b>Cash and cash equivalents at end of period</b>       | <b>5,745</b>                               | <b>17,008</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 30, 2015.