TRINITY BIOTECH PLC
Form 6-K
July 30, 2013

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 July, 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 July 30, 2013

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

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Trinity Biotech Announces Quarter 2 Financial Results and

Acquisition of Immco Diagnostics Inc.

DUBLIN, Ireland (July 30, 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 June 30, 2013 and the acquisition of Immco Diagnostics Inc.

Quarter 2 Results

Total revenues for Q2, 2013 were $21.3m which compares to $20.8m in Q2, 2012, an increase of 2.4%.

Point-of-Care revenues for Q2, 2013 increased by 4% when compared to Q2, 2012. This increase was mainly attributable to continued strong demand for HIV products in Africa.

Clinical Laboratory revenues increased from $16.4m to $16.7m, which represents an increase of 2% compared to Q2, 2012. However, due to an unprecedented cold winter and late snowfalls in north-eastern USA, Lyme sales were approximately $750k lower year on year. Meanwhile, non-Lyme sales for the quarter increased by approximately 8%.

Revenues for Q2, 2013 by key product area were as follows:

	2012 Quarter 2 US$ 000	**2013 Quarter 2 US$ 000**	**Increase %**
Point-of-Care	4,410	4,586	4.0%
Clinical Laboratory	16,399	16,726	2.0%
Total	***20,809***	***21,312***	***2.4%***

Gross profit for Q2, 2013 amounted to $10.6m representing a gross margin of 49.8%, which is lower than the 51.6% achieved in Q2, 2012. This decrease is attributable primarily to the impact of lower margins on Premier instrument sales but also due to lower sales of higher margin Lyme products.

Research and Development expenses have increased from $0.8m to $0.9m when compared to the equivalent quarter last year. Meanwhile, Selling, General and Administrative (SG&A) expenses have increased over the same period from $5.2m to $5.5m. This increase was due to the acquisition costs of $0.4m associated with the Immco acquisition.

Operating profit has decreased from $4.3m to $3.8m for the quarter, again reflecting the impact of the Immco acquisition costs. If such costs were excluded, the operating margin in the quarter would have been 19%.

Net financial income was approximately $0.4m and represents a decrease compared to Q2, 2012 due to lower prevailing deposit interest rates.

The tax charge for Q2, 2013 was $0.3m which represents an effective tax rate of approximately 6.5%.

Profit After Tax before the Medical Device Excise Tax (MDET) decreased from $4.3m to $4.0m. However, excluding the impact of the Immco acquisition costs, profits increased from $4.3m to $4.4m. EPS (excluding MDET) for the quarter was 18.5 cents. However, if the impact of the Immco acquisition costs were excluded, this would increase to 20.5 cents compared to 20 cents in Q2, 2012.

Earnings before interest, tax, depreciation, amortisation and share option expense for the quarter was $5.1m.

Recent Developments

Cardiac Update

The development of our new cardiac point-of-care tests is progressing very well and our projected launch dates remain on target. Last quarter, we announced that we had reached design freeze on our high sensitivity Troponin I test and that we were commencing the clinical trials necessary to obtain CE marking. As part of this process, our Troponin I test is currently participating in the FASTEST study currently being undertaken in Sweden. This study, under the sponsorship and guidance of Professor Bertil Lindal and Uppsala Clinical Research, is designed to measure Troponin I levels in serial early samples in patients with symptoms suggestive of ACS (Acute Coronary Syndrome). Six emergency rooms at major hospitals are participating in this multi-site study. In parallel, a study of normal subjects is being conducted by Scandinavian CRO AB. Consequently, we expect to obtain CE marking in December, 2013 at which point the product will be authorised for sale throughout the European Union. We are currently appointing distributors throughout the EU and expect first sales of the Troponin test in early 2014.

In terms of the US market, protocols have now been completed for the FDA clinical trials for which Professor Fred Apple, Minneapolis, will be the Principal Investigator. Five nationwide sites have been selected and we are currently completing the necessary contractual and ethical approval processes in order for the US trials to commence. These trials will commence in October/November and will be completed by the end of quarter 1, 2014, with FDA approval anticipated by the end of 2014.

Meanwhile, work on our BNP assay also continues to progress very well and the product is expected to be ready to commence CE trials later this year with a view to obtaining CE marking in Q1, 2014 with sales commencing shortly thereafter.

Finally, during the quarter, the company hired Mr. Tom Parenteau to head up our Cardiovascular Sales Division. Tom, who has more than 20 years of commercial experience in the diagnostics industry, most recently worked with Alere/Biosite as Senior Director of Global Marketing, heading up Alere s Cardiovascular Products Division. Tom brings to the company the requisite knowledge and experience of the cardiovascular market required for a successful launch of Trinity s Troponin and BNP products.

Premier sales

Sales of our diabetes instrument, Premier, continue to perform strongly. During quarter 2, 80 instruments were sold compared to 67 instruments in quarter 1, 2013. This included the first sales of instruments to China following the receipt of Chinese regulatory approval. With total sales of 147 instruments for the first half of 2013, the Company is confident of meeting its target of 320 instruments for the year as a whole.

Dividend

In June 2013, the company paid a dividend of 20 US cents per ADR, which represents an increase of 33% compared with 15 US cents per ADR paid in 2012.

Acquisition of Immco Diagnostics Inc.

Trinity Biotech is pleased to announce the acquisition of Immco Diagnostics Inc. (Immco) on July 26, 2013, for a consideration of $32.75m. Headquartered in Buffalo, New York, and employing 90 people, Immco is a diagnostic company specializing in the development, manufacture and sale of autoimmune test kits on a worldwide basis. This product line is complemented by specialized reference laboratory services in diagnostic immunology, pathology and immunogenetics, marketed to US-based reference laboratories and hospitals. Immco is currently generating revenues of $12.5m, ($8.5m of product revenues and $4m of laboratory revenues) and following acquisition and initial integration costs, will become immediately earnings accretive.

It is Trinity Biotech s intention to retain Immco s existing management team which, led by Mr. Bill Maggio, has a proven track record and expertise in growing a successful autoimmune business.

Currently, over 50 million Americans are affected by more than 80 different autoimmune diseases. Autoimmune diseases are now the second leading cause of chronic illness and the leading cause of death amongst women over 65. The autoimmune market is divided into two main segments, the first of which is the automated, high volume segment for standard analytes such as thyroid markers. This segment is dominated by the large diagnostic players such as Abbott, Roche and Beckman Coulter, is growing slowly and is one where Immco does not participate.

Instead, Immco s position is in the $250m, high growth (over 10% p.a.), lower throughput, speciality autoimmune segment, where the competition is limited to a small number of key players, principally Bio-Rad, Werfen-Inova and Phadia. The principal autoimmune conditions in this segment are Rheumatoid Arthritis, Vasculitis, Lupus, Celiac and Crohn s disease, Ulcerative Colitis, Neuropathy, Hashimoto s and Graves disease. Meanwhile, the two key technologies employed are Immunoflourescence (IFA) and Immunoassay (EIA). Immco offers a comprehensive range of more than 120 products across all the main autoimmune segments with its EIA product range running on the DSX/DS2 Instrument platform while the IFA products are capable of being read manually or on Immco s proprietary IFA reading system, iSight. In terms of range, breadth and technical performance, the Immco IFA range is best on the market, while the EIA range is of the highest quality and very competitive with the market leaders.

Immco currently sells its products through a network of distributors, mainly outside the USA. In Europe, Immco s main distribution partner is Menarini, a company with which Trinity already has deep distribution ties. The broadening of the relationship between Menarini and Trinity through the additional distribution of the Immco product is viewed very positively by all parties. To date Immco has had very low product sales in the USA due to a lack of FDA product approvals and sales force. However, over the past 24 months, Immco has been successful in harmonizing its complete IFA and EIA product ranges, virtually all of which have now been FDA 510K cleared. Through Trinity Biotech s existing US based sales force (which already sells approximately $2m of Trinity s own autoimmune products) and installed base of EIA instrumentation, Trinity expects to immediately launch Immco s products in the USA. Moreover, as the Immco autoimmune product range complements Trinity s existing infectious disease EIA range, we intend that our large range of installed DSX and DS2 instruments which currently run our infectious disease product line will now also run the entire Immco autoimmune EIA range. We believe that this in turn will help drive growth in both ranges of products due to the synergistic effect of a broader menu offering.

Immco is further driving expansion with the development of a number of new diagnostic kits, such as the ImmuLisa Enhanced Cardiolipin Antibody ELISAs recently cleared by the FDA, and there is a robust pipeline of novel assays in development. Meanwhile, the Immco reference laboratory is in the process of launching exclusive panels of tests for Sjögren s Syndrome and Chronic Rhinosinusitus, both of which are significantly underdiagnosed conditions with high incidence.

In summary, Trinity expects to grow Immco s revenues by

- harnessing the breadth, quality and uniqueness of Immco s product range, in the context of only recently having obtained FDA approval;
- leveraging Trinity s sales force and in particular, installed instrument base in the USA;
- leveraging Trinity s international distributor network;
- introducing new innovative autoimmune products which are now beginning to emerge from the development phase; and
- exploiting the synergies that exist between Trinity s existing infectious diseases and Immco s autoimmune product ranges.

Based on these factors it is believed that this business can grow at a rate in excess of 20% per annum.

Comments

Commenting on the results, Kevin Tansley, Chief Financial Officer, said On a like for like basis, profits for this quarter increased from $4.3m to $4.4m. This equates to an increase in EPS from 20 cents to 20.5 cents. This was achieved despite significantly lower sales of Lyme test kits in the USA due to weather related conditions.

Ronan O Caoimh, CEO, stated Firstly, we are pleased to have completed the acquisition of Immco which has a truly excellent and complete range of autoimmune products with, in our opinion, the best IFA range in the world and an ELISA range that matches the quality of the market leaders. In addition, it also has a very exciting and innovative product development pipeline. The autoimmune market is currently growing at a rate well above the overall diagnostics market and this product range fits very well with our existing infectious diseases product offering. Trinity already has a large installed base of DSX instruments which run our infectious diseases product range and it is expected that these instruments will now also run the Immco range of autoimmune products. Further synergies will be achieved by leveraging Trinity s existing US sales force and international distributor network. Due to these factors we expect the Immco product line to be a significant driver of growth for Trinity, both from a revenue and profitability point of view.

I would also like to point out that this quarter the Company has made excellent progress in its key strategic areas. Our high sensitivity Troponin I test is currently participating in CE marking trials in Europe, with a view to obtaining its CE mark in December this year. Our BNP test will follow closely after, with its CE marking trials expected to commence in Q4, 2013. Meanwhile, from a diabetes perspective, we were successful in placing 80 new Premier instruments during the quarter including our first sales to China.

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 June 30, 2013** **(unaudited)**	**Three Months Ended June 30, 2012** **(unaudited)**	**Six Months Ended June 30, 2013** **(unaudited)**	**Six Months Ended June 30, 2012** **(unaudited)**
Revenues	**21,312**	**20,809**	**41,640**	**40,835**
Cost of sales	(10,691)	(10,071)	(20,681)	(19,754)
Gross profit	**10,621**	**10,738**	**20,959**	**21,081**
Gross profit *%*	*49.8%*	*51.6%*	*50.3%*	*51.6%*
Other operating income	85	114	195	289
Research & development expenses	(924)	(753)	(1,779)	(1,598)
Selling, general and administrative expenses	(5,502)	(5,240)	(10,535)	(10,444)
Indirect share based payments	(440)	(563)	(938)	(900)
Operating profit	**3,840**	**4,296**	**7,902**	**8,428**
Financial income	466	605	943	1,151
Financial expenses	(26)	(35)	(52)	(36)
Net financing income	440	570	891	1,115
Profit before tax	**4,280**	**4,866**	**8,793**	**9,543**
Income tax expense	(278)	(564)	(452)	(1,131)
Profit for the period before MDET	**4,002**	**4,302**	**8,341**	**8,412**
Medical device excise tax (MDET)	(174)		(345)	
Profit for the period after MDET	**3,828**	**4,302**	**7,996**	**8,412**
Earnings per ADR (US cents)	17.7	20.0	36.8	39.4
Diluted earnings per ADR (US cents)	16.9	19.2	34.9	37.7
Earnings per ADR excluding MDET (US cents)	18.5	20.0	38.4	39.4
Diluted earnings per ADR excluding MDET (US cents)	17.6	19.2	36.4	37.7
Weighted average no. of ADRs used in computing basic earnings per ADR	21,665,259	21,465,047	21,732,983	21,341,365
Weighted average no. of ADRs used in computing diluted earnings per ADR	22,711,752	22,439,332	22,935,565	22,307,429

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

	June 30, 2013 US$ 000 (unaudited)	March 31, 2013 US$ 000 (unaudited)	Dec 31, 2012 US$ 000 (audited)
ASSETS			
Non-current assets			
Property, plant and equipment	10,189	9,331	8,883
Goodwill and intangible assets	80,489	76,748	73,046
Deferred tax assets	4,872	4,533	4,073
Other assets	1,065	945	908
Total non-current assets	96,615	91,557	86,910
Current assets			
Inventories	22,923	23,110	20,757
Trade and other receivables	17,426	15,299	14,457
Income tax receivable	315	322	336
Cash and cash equivalents	66,164	73,095	74,947
Total current assets	106,828	111,826	110,497
TOTAL ASSETS	203,443	203,383	197,407
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the parent			
Share capital	1,158	1,143	1,134
Share premium	5,858	5,449	5,138
Accumulated surplus	163,338	163,886	158,973
Other reserves	4,463	4,128	4,135
Total equity	174,817	174,606	169,380
Current liabilities			
Income tax payable	1,234	1,261	1,092
Trade and other payables	13,344	12,955	11,824
Provisions	50	50	50
Total current liabilities	14,628	14,266	12,966
Non-current liabilities			
Other payables	2,325	3,344	4,318
Deferred tax liabilities	11,673	11,167	10,743
Total non-current liabilities	13,998	14,511	15,061
TOTAL LIABILITIES	28,626	28,777	28,027
TOTAL EQUITY AND LIABILITIES	203,443	203,383	197,407

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

(US$000 s)	**Three Months Ended June 30, 2013**	**Three Months Ended June 30, 2012**	**Six Months Ended June 30, 2013**	**Six Months Ended June 30, 2012**
	(unaudited)	**(unaudited)**	**(unaudited)**	**(unaudited)**
Cash and cash equivalents at beginning of period	**73,095**	**65,499**	**74,947**	**71,085**
Operating cash flows before changes in working capital	4,887	5,610	10,064	10,725
Changes in working capital	(2,793)	(770)	(5,344)	(2,591)
Cash generated from operations	2,094	4,840	4,720	8,134
Net Interest and Income taxes received	367	26	799	501
Capital Expenditure & Financing (net)	(5,019)	(2,770)	(9,929)	(5,157)
Free cash flow	(2,558)	2,096	(4,410)	3,478
Proceeds from sale of Coagulation product line		11,250		11,250
Cash paid to acquire Fiomi Diagnostics				(5,624)
Cash paid to acquire Phoenix Bio-tech				(333)
Dividend payment	(4,373)	(3,223)	(4,373)	(3,223)
Repurchase of own company shares		(2,017)		(3,028)
Cash and cash equivalents at end of period	**66,164**	**73,605**	**66,164**	**73,605**

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: July 30, 2013.