TRINITY BIOTECH PLC
Form 6-K
August 05, 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 July, 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 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 29, 2014

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Trinity Biotech Announces Quarter 2 Financial Results

25% Increase in Operating Profits

DUBLIN, Ireland (July 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 June 30, 2014.

Quarter 2 Results

Total revenues for Q2, 2014 were $26.0m compared to $21.3m in Q2, 2013, which represents an increase of 22%.

Point-of-Care revenues for Q2, 2014 were $4.6m and broadly in line with the comparative quarter last year. Clinical Laboratory revenues increased from $16.7m to $21.4m, which represents an increase of 27.9% compared to Q2, 2013. This growth was achieved through a combination of acquisition revenues and higher diabetes revenues as partially offset by slightly lower Lyme and Fitzgerald sales.

Revenues for Q2, 2014 by key product area were as follows:

	2013 Quarter 2 US$ 000	**2014 Quarter 2 US$ 000**	**Increase %**
Point-of-Care	4,586	4,615	0.6%
Clinical Laboratory	16,726	21,390	27.9%
Total	***21,312***	***26,005***	***22.0%***

Gross profit for Q2, 2014 amounted to $12.5m representing a gross margin of 48.1%, which is slightly lower than the 49.0% achieved in Q2, 2013. This decrease is primarily attributable to the impact of lower margins on Premier instrument sales, but also due to additional costs associated with running two manufacturing facilities in the UK. Production of blood banking products at these facilities ceased at the end of June and was transferred to other company facilities in the USA and Ireland.

Research and Development expenses have increased from $0.9m to $1.2m when compared to the equivalent quarter last year. Meanwhile, Selling, General and Administrative (SG&A) expenses have increased over the same period from $5.5m to $6.4m. In both cases, the increase was primarily due to the impact of the Immco and blood bank screening acquisitions, both of which were undertaken in the second half of 2013.

Operating profit has increased from $3.7m to $4.6m for the quarter, which equates to an increase of 25% and represents an operating margin of 17.7%.

Financial income was broadly offset by financial expenses resulting in a negligible net expense for the quarter. This compares to net financial income of approximately $0.4m earned in Q2, 2013. This is due to lower funds being placed on deposit following the utilisation of funds for the Immco and blood banking acquisitions and lower prevailing deposit interest rates.

The tax charge for Q2, 2014 was $0.3m which equates to an effective tax rate of approximately 6%.

Profit before tax increased from $4.1m to over $4.6m which represents an increase of approximately 12%. Meanwhile, profit after tax increased from $3.8m to $4.3m, an increase of 13%. EPS for the quarter was 19.0 cents which compares to 17.7 cents for the equivalent period last year.

Earnings before interest, tax, depreciation, amortisation and share option expense for the quarter was $6.0m. This compares to $5.1m for Q2, 2013.

Recent Developments

Cardiac Update

In quarter 1, 2014 the company obtained CE marking for the Meritas Troponin I test, our new high sensitivity Troponin product. The product is currently undergoing clinical evaluation in all major European markets in advance of commercial rollout. Meanwhile, for the purpose of FDA approval, the Meritas Troponin I test is undergoing clinical evaluation at multiple trial sites across the USA. To date, six US trial sites have been enrolling patients for the Acute Coronary Syndrome (ACS) study and over the coming weeks we intend to increase the number of trial sites to 10. We are currently recruiting ACS patients at a rate of approximately 40 per week. With the additional trial sites coming on line, we envisage that enrolment rates will reach 80 to 100 patients per week. At this level of recruitment, sufficient ACS data is expected to be available by mid-Q4 2014, with clinical adjudication to follow immediately thereafter and submission to the FDA targeted for the end of 2014. Meanwhile, enrolment for our Normals (99th percentile) study is progressing according to plan at three trial sites and is expected to be completed well in advance of the ACS trial.

Furthermore, Dr. Fred Apple (Medical Director at Hennepin County Medical Center, Minneapolis and Key Opinion Leader in cardiology) presented the results of an independent clinical evaluation he has carried out on the Meritas Troponin I product at this week s AACC annual meeting in Chicago. His results indicate that the Meritas product has a diagnostic accuracy far in advance of any of the existing point-of-care Troponin tests and indeed in many cases is as good as, if not better than, some of the central laboratory Troponin products currently available on the US market. Dr Apple concludes that this study validates the Meritas Troponin I test as an appropriate tool for both ruling in and ruling out myocardial infarction in the emergency room setting. Moreover, this study was constructed in a fashion that mirrors the ACS trial required by the FDA. The results of Dr. Apple s independent trial, in addition to the results of the trials carried out for CE marking, provide us with a high degree of confidence that the Meritas Troponin product has the necessary performance characteristics to meet and indeed exceed the FDA s new stringent performance specifications for Troponin testing.

During the quarter, significant progress has been made in completing the development of our Meritas BNP product for detection of heart failure. The clinical trials necessary to obtain CE marking are virtually complete and we expect to submit for CE clearance during the month of August. This will be immediately followed by the commencement of US clinical trials, with FDA submission expected before the end of 2014. Meanwhile, development of our Meritas D-dimer product, a test for Pulmonary Embolism and DVT (deep vein thrombosis) is progressing very well and according to schedule.

Premier Update

Sales of our diabetes instrument, Premier, continue to perform strongly. During the quarter, 106 instruments were sold or placed with customers. This compares with 80 instruments for the equivalent period last year. This brings the total sales or placements of instruments for the first half of 2014 to 207. On this basis, we are in line to achieve our target of 460 for the year as a whole.

During the quarter, we also formally launched our new Premier Resolution instrument. This version of the instrument has been specifically designed for the detection and identification of haemoglobin variants as opposed to A1c (diabetes) testing which is currently undertaken by the existing Premier instrument. Prior to this Trinity had only limited presence in the variant market, being largely concentrated in the high throughput end of the US market with the Ultra instrument. Going forward Premier Resolution, which will act as a companion instrument for the Premier, will provide greater access to this segment of the market. Following its launch the first instruments have already been placed in the United Kingdom.

Immco Update

The Immco acquisition has been performing well and has now been fully integrated into the Trinity group. We are particularly pleased with the opportunity that Sjö , Immco s test for the early detection for Sjögren s syndrome, represents. Towards the end of the quarter, in conjunction with our partner, Nicox, this test was rolled out nationally in the USA. Prior to this, it has only been available in a number of selected US markets where initial indicators had demonstrated that the product was well received and for which there was strong demand. Since then, we have extended Nicox s rights to this product to cover all healthcare practitioners in North America previously it had been limited to the ophthalmic segment of the market.

Sjögren s syndrome is a very prevalent though widely under-diagnosed debilitating condition of which dry eye is one of the primary symptoms. Immco s Sjö test is the only approved test for Sjögren s syndrome in the USA.

Dividend

Shareholder approval for payment of a dividend of 22 US cents per ADR, was granted at the company s AGM, which was held on 6 June, 2014. This represents an increase of 10% compared with 20 US cents per ADR paid in 2013. Payment of the dividend was made in July 2014.

Comments

Commenting on the results, Kevin Tansley, Chief Financial Officer, said This quarter we achieved impressive profitability growth with operating profit growing by 25% and profit after tax rising by almost 13%. This was achieved notwithstanding increased marketing costs for our new cardiac product range and increased placements of Premier instruments which tend to have lower margins. In addition, this quarter s results were impacted by running duplicate facilities in the United Kingdom for our blood bank screening business. Production at these facilities has now ceased and they will be fully vacated by the end of this month resulting in cost savings from quarter 3 onwards.

Ronan O Caoimh, CEO, stated The clinical trials for our new Troponin I test on the Meritas platform are now well underway. To date these trials have been progressing more slowly than we would have wanted. This has been solely attributable to slower than expected recruitment of patients for the trials due to the nature of the testing protocol that we are required to adhere to. In order to avoid any delay in submitting the results to the FDA, we have increased the number of trial sites from the six existing sites to 10 sites in total. Recruitment at the new sites will commence imminently. Meanwhile, we were very pleased with the performance of the test in Dr. Apple s Troponin trial results, which were published yesterday at the AACC annual meeting in Chicago. These results, we believe, demonstrated the unparalleled specificity and sensitivity of the product in the point-of-care environment, thus reinforcing its capability as both a rule in and rule out test.

Meanwhile, our BNP test on the same platform is nearing the completion of its CE marking trials. The results of these trials have been showing excellent performance and consequently we expect to announce European regulatory approval in the coming weeks. Once this has been achieved we will immediately commence our FDA trials. By their nature these trials will be more straight forward than the Troponin trials and thus we expect to be in a position to submit this product to the FDA for approval by the end of 2014.

I am also pleased to report that our Immco product line continues to perform very well. In particular, we believe the company s Sjö test for the early detection of Sjögren s syndrome represents a significant growth opportunity for the company. The product has already been well received in a number of test markets in the USA. Consequently, in conjunction with our partner, Nicox, it has now been rolled out nationally in the USA where we believe it will gain significant traction.

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

	Three Months Ended June 30, 2014	Three Months Ended June 30, 2013	Six Months Ended June 30, 2014	Six Months Ended June 30, 2013
(US$000 s except share data)	**(unaudited)**	**(unaudited)**	**(unaudited)**	**(unaudited)**
Revenues	**26,005**	**21,312**	**51,030**	**41,640**
Cost of sales	(13,496)	(10,865)	(26,360)	(21,026)
Gross profit	**12,509**	**10,447**	**24,670**	**20,614**
Gross profit %	*48.1%*	*49.0%*	*48.3%*	*49.5%*
Other operating income	98	85	248	195
Research & development expenses	(1,155)	(924)	(2,192)	(1,779)
Selling, general and administrative expenses	(6,417)	(5,502)	(12,730)	(10,535)
Indirect share based payments	(442)	(440)	(897)	(938)
Operating profit	**4,593**	**3,666**	**9,099**	**7,557**
Financial income	42	466	84	943
Financial expenses	(44)	(26)	(64)	(52)
Net financing income / (expense)	(2)	440	20	891
Profit before tax	**4,591**	**4,106**	**9,119**	**8,448**
Income tax expense	(276)	(278)	(391)	(452)
Profit for the period	**4,315**	**3,828**	**8,728**	**7,996**
Earnings per ADR (US cents)	19.0	17.7	38.6	36.8
Diluted earnings per ADR (US cents)	18.2	16.9	36.8	34.9
Weighted average no. of ADRs used in computing basic earnings per ADR	22,703,261	21,665,259	22,584,889	21,732,983
Weighted average no. of ADRs used in computing diluted earnings per ADR	23,686,336	22,711,752	23,720,056	22,935,565

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, 2014 US$ 000 (unaudited)	March 31, 2014 US$ 000 (unaudited)	Dec 31, 2013 US$ 000 (audited)
ASSETS			
Non-current assets			
Property, plant and equipment	14,784	13,841	12,991
Goodwill and intangible assets	137,848	133,881	128,547
Deferred tax assets	9,082	7,570	7,044
Other assets	1,222	1,131	1,162
Total non-current assets	162,936	156,423	149,744
Current assets			
Inventories	33,109	30,864	29,670
Trade and other receivables	27,163	24,130	24,268
Income tax receivable	88	493	487
Cash and cash equivalents	15,153	17,008	22,317
Total current assets	75,513	72,495	76,742
TOTAL ASSETS	238,449	228,918	226,486
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the parent			
Share capital	1,202	1,187	1,170
Share premium	12,097	9,731	8,842
Accumulated surplus	179,137	174,023	168,670
Other reserves	3,672	4,073	4,329
Total equity	196,108	189,014	183,011
Current liabilities			
Income tax payable	1,036	998	770
Trade and other payables	16,106	15,679	20,131
Provisions	75	75	75
Total current liabilities	17,217	16,752	20,976
Non-current liabilities			
Other payables	4,665	4,634	4,596

Deferred tax liabilities	20,459	18,518	17,903
Total non-current liabilities	25,124	23,152	22,499
TOTAL LIABILITIES	42,341	39,904	43,475
TOTAL EQUITY AND LIABILITIES	238,449	228,918	226,486

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Trinity Biotech plc

Consolidated Statement of Cash Flows

(US$000 s)	**Three Months Ended June 30, 2014** **(unaudited)**	**Three Months Ended June 30, 2013** **(unaudited)**	**Six Months Ended June 30, 2014** **(unaudited)**	**Six Months Ended June 30, 2013** **(unaudited)**
Cash and cash equivalents at beginning of period	**17,008**	**73,095**	**22,317**	**74,947**
Operating cash flows before changes in working capital	5,919	4,887	10,911	10,064
Changes in working capital	(4,309)	(2,793)	(9,571)	(5,344)
Cash generated from operations	1,610	2,094	1,340	4,720
Net Interest and Income taxes received	611	367	614	799
Capital Expenditure & Financing (net)	(4,076)	(5,019)	(9,118)	(9,929)
Free cash flow	(1,855)	(2,558)	(7,164)	(4,410)
Dividend payment		(4,373)		(4,373)
Cash and cash equivalents at end of period	**15,153**	**66,164**	**15,153**	**66,164**

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 29, 2014.