TRINITY BIOTECH PLC
Form 6-K
March 18, 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 March, 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 March 4, 2014

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Trinity Biotech Announces Results for Q4 and Fiscal Year 2013

Q4 Operating profit grows by 15%

DUBLIN, Ireland (March 4, 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 fiscal year 2013 and the quarter ended December 31, 2013.

Fiscal year 2013 Results

Total revenues for fiscal year 2013 were $91.2m versus $82.5m in 2012, thus representing an increase of 10.6% year on year.

Point-of-care revenues increased by over 3% from $19.2m in 2012 to $19.8m in 2013. This growth was due to the continuing strength of HIV sales in Africa.

Meanwhile, Clinical Laboratory revenues grew by almost 13% and this was due to a number of factors as follows:

higher Diabetes sales driven by increased Premier placements;

the impact of the Immco and blood bank screening acquisitions made during the year; and

higher sales of infectious diseases products in China.

This was partly offset by lower Lyme sales due to the impact of adverse weather conditions in eastern USA, particularly in the first half of 2013.

Revenues for Q4 and fiscal year 2013 by key product area were as follows:

	2012 Quarter 4 US$ 000	2013 Quarter 4 US$ 000	Q4 2013 vs Q4 2012 %	Full Year 2012 US$ 000	Full Year 2013 US$ 000	Full Year 2013 vs 2012 %
Point-of-Care	4,872	5,088	4.4%	19,154	19,754	3.1%
Clinical Laboratory	15,952	20,367	27.7%	63,356	71,462	12.8%
Total	**20,824**	**25,455**	**22.2%**	**82,510**	**91,216**	**10.6%**

The other key financial results for 2013 were as follows:

Operating profit grew by 4.1% from $17.2m to $17.9m. This represents an operating margin of 19.6%.

Profit before Medical Device Excise Tax (MDET) and once-off charges increased from $17.3m to $17.8m, representing an annual growth rate of 3%.

EBITDA and before share option expense for the year increased from $21.7m to $23.5m.

The above items are before the impact of once-off charges associated with taking a HIV-2 licence and restructuring costs associated with the blood bank screening business acquired from Lab21.

Overall the profit for the year was impacted by a number of factors:

Prior to the launch of our new cardiac products, the company has started to put in place a sales and marketing function dedicated to the launch and support of these products. To date the cost of this function has not been offset by any associated revenues, which are only due to commence in 2014;

Higher running costs associated with the two blood bank screening manufacturing facilities in the UK. These facilities will be closed in mid-2014, following the transfer of manufacturing to Trinity s facilities in Ireland and New York; and

Integration and transaction costs incurred in Immco in the period post acquisition.

The tax charge for the year was 6.75% which compares favourably to the 10.4% reported in 2012. This low taxation rate reflects the advantage of the low corporate tax rates and R&D tax credits which apply in Ireland.

Key Achievements in 2013

Cardiac

2013 was a key year for the development of our new point-of-care products on our Meritas platform. In particular, we achieved design freeze on our Troponin I test during quarter 2, which was then followed by CE marking trials during the second half of the year. The results demonstrated in these trials were excellent and consequently CE marking (effectively EU regulatory approval) was obtained in early 2014. The Meritas Troponin test demonstrates unrivalled sensitivity and precision in the point-of-care environment making it the only test on the market capable of detecting heart attacks in accordance with all of the performance guidelines issued by the world s leading cardiac organisations. FDA trials for this product are now about to commence in the USA. Based on its high clinical and guideline compliant performance, we are confident of meeting and indeed exceeding the stringent requirements for FDA approval. FDA submission is targeted for the second half of 2014 with approval anticipated in early 2015.

In addition, we made significant progress on the second test to be launched on the Meritas platform, BNP a test for determining risk of heart failure. We are anticipating obtaining CE Marking for this product in mid-2014 with FDA submission to follow in Q4 2014. We have now identified D-dimer as the next product to be launched on this platform and have already commenced the development process. Trinity will take advantage of the high precision testing, which this unique technology is capable of, to develop a range of other point-of-care tests on this platform.

Premier

It was another very successful year for our new diabetes instrument, the Premier. We achieved our target for instruments shipped during 2013 with strong sales in a wide range of markets including USA, Europe, China,

South-East Asia and South America. The most important development during 2013 was obtaining regulatory approval for the instrument in China, a market in which we believe we can sell in excess of 100 instruments p.a. We are also very pleased to announce that we have just obtained regulatory approval in Brazil and are expecting to make our first sales of Premier instruments in Q1, 2014. We also completed development of the ion exchange version of the Premier, which will have particular applicability in certain geographic areas, such as the Mediterranean region.

Acquisition of Immco

In Q2, 2013 we acquired Immco Diagnostics Inc. for $32.9m. Immco is a Buffalo based diagnostics company, which specialises in the development, manufacture and sale of autoimmune products. The product line, which is fully FDA approved, is complemented by a US reference laboratory business offering specialised immunology, pathology and immunogenetics testing. The company possesses the best range of IFA autoimmune products in the world and an ELISA range of products that at least matches the market leaders. Trinity expects to grow the business by 20% p.a. This will be achieved by leveraging Trinity s sales force and instrument base in the USA, using Trinity s established international distributor network to reach new markets and by exploiting the synergies between Trinity s existing infectious diseases and Immco s autoimmune product ranges. In addition, at the time of acquisition Immco was in the process of launching a number of recently developed products including a new test for detecting Sjogren s Syndrome.

Acquisition of blood bank screening business from Lab21

In Q4, 2013 we announced the acquisition of the blood bank screening business of UK based diagnostics company Lab21 Limited for $7.5m. The business includes high quality TPHA and ELISA products for screening blood banks with a particular emphasis on syphilis and malaria testing. The syphilis products acquired already have a market share of over 75% of the syphilis blood bank markets in the UK, France, Germany, Netherlands, Switzerland, Austria and Belgium. It is Trinity s intention to further grow the business by expanding beyond its traditional markets in Western Europe, by bringing its products to the USA and developing markets. We are also in the process of transferring its manufacturing operations from its existing UK plants to Trinity s facilities in Ireland and the USA.

Rapid products

During 2013, we obtained CE marking for a number of our rapid point-of-care tests being developed in our San Diego facility. We now have nine new point-of-care tests which have been CE marked and are being launched through a wide range of distributors within Europe. In addition to having been CE marked, the tests for Cryptosporidium, Giardia, Syphilis and HSV2 are also FDA approved whilst our H-pylori test will be submitted to the FDA in Q3 2014.

HIV-2 Claim

Trinity obtained FDA approval for a HIV-2 claim for its Uni-Gold platform Recombigen® HIV rapid product. Previously the product had a claim for HIV-1 only. This had restricted the market in which Trinity was able to compete as some health body tenders required both strains to be detectable. Furthermore, Trinity had been at a competitive disadvantage due to the more favourable reimbursement rates paid in respect of HIV-1/2 testing versus HIV-1 only. Management believe that this new claim will enable this product to grow in the years ahead following a 4-5% decline in recent years due to reduced federal funding for HIV testing.

Dividend

The annual dividend was increased by 33% from 15 cents per ADR to 20 cents per ADR. This follows an increase in the previous year from 10 cents to 15 cents.

Quarter 4 Results

Total revenues for Q4, 2013 were $25.5m which compares to $20.8m in Q4, 2012, an increase of 22.2%.

Point-of-Care revenues for Q4, 2013 increased by 4.4% when compared to Q4, 2012. This increase reflects the growth in HIV revenues in Africa.

Clinical Laboratory revenues increased from $16.0m to $20.4m, which represents an increase of 27.7% compared to Q4, 2012. This was partly due to the impact of acquisitions, increased Premier revenues and higher sales of infectious diseases products in China.

Gross margin for the quarter was 50.4% which is slightly lower that the 50.6% reported in Q4, 2012.

Research and Development expenses were $1.0m, which represents an increase of 35% compared to the corresponding period last year. Meanwhile, Selling, General and Administrative (SG&A) expenses have also increased, from $5.2m to $6.5m. In both cases, the increase was primarily attributable to the impact of acquisitions undertaken during 2013.

Operating profit for the quarter was over $5.0m, which represents an increase of approximately 15% over the $4.4m reported in Q4, 2012. The operating margin for the quarter was 19.8%.

Profit before tax increased from $4.9m to $5.2m, while profit after tax increased from $4.5m to $4.8m, an increase of over 8%. Meanwhile, EPS for the quarter increased by 4% from 20.8 cents to 21.7 cents. Each of the above metrics is before the impact of the Medical Device Excise Tax (MDET) which was introduced in 2013.

Comments

Commenting on the Q4, 2013 results, Kevin Tansley, Chief Financial Officer, said We achieved very strong operating profits during the quarter. The increase from $4.4m to over $5m represented an increase of 15% quarter on quarter, which equates to an operating margin of approximately 20%. We have continued our trend of growing profit after tax which increased by 8% for the quarter. EPS for the quarter grew from 20.8 cents to 21.7 cents versus the same quarter last year.

Ronan O Caoimh, CEO of Trinity said

During 2013, we focussed on identifying, creating and developing a range of growth opportunities. Of key importance was the completion of our Meritas Troponin test the only point-of-care test capable of detecting heart attacks in the point-of-care environment in accordance with the guidelines issued by the world s leading cardiac organisations. Successful clinical trials carried out in late 2013, demonstrated excellent results in the emergency room environment and resulted in the granting of EU regulatory approval. This will soon be followed by FDA submission, which is targeted for the second half of 2014. FDA approval will give us access to a $350m market with a unique and best-in-class product. We also made significant progress with our test for BNP, which will be the next test to be launched on the Meritas platform, and one which has a market size of $300m. CE marking for this product is expected in mid-2014, to be followed by FDA submission in Q4 2014. These two tests, in addition to a range of other tests which we intend to launch on this platform will serve as a major revenue growth engine for the company in the years ahead.

We were also successful in continuing to grow our diabetes business particularly on our Premier platform. Of critical importance was obtaining regulatory approval in China where we have already made significant instrument sales. Similarly, I am very happy to be announcing today that we have now received regulatory approval for the Premier in Brazil, where we expect to make immediate and significant inroads in to what is a very large and growing market.

During 2013, we also completed two acquisitions the Buffalo based autoimmune diagnostics company, Immco Diagnostics, and the blood bank screening business of Lab21 Limited in the UK. Both of these have excellent quality products, making them ideally suited to take advantage of the growing sectors of the diagnostics markets in which they compete. This growth will be further augmented by exploiting the many synergies which will come from integrating these entirely complementary product lines into Trinity s existing product offering and taking advantage of our US sales force and international distribution network.

I believe that the company is now ideally positioned for a period of strong growth across a range of product lines with a particular emphasis on high growth geographic and product markets.

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 Dec 31, 2013**	**Three Months Ended Dec 31, 2012**	**Year Ended Dec 31, 2013**	**Year Ended Dec 31, 2012**
	(unaudited)	**(unaudited)**	**(unaudited)**	**(unaudited)**
Revenues	**25,455**	**20,824**	**91,216**	**82,510**
Cost of sales	(12,637)	(10,290)	(45,305)	(40,257)
Gross profit	**12,818**	**10,534**	**45,911**	**42,253**
Gross profit %	*50.4%*	*50.6%*	*50.3%*	*51.2%*
Other operating income	247	93	532	468
Research & development expenses	(1,035)	(765)	(3,691)	(3,130)
Selling, general and administrative expenses	(6,481)	(5,159)	(22,901)	(20,750)
Indirect share based payments	(521)	(314)	(1,978)	(1,675)
Operating profit	**5,028**	**4,389**	**17,873**	**17,166**
Financial income	132	532	1,300	2,280
Financial expenses		(26)	(75)	(88)
Net financing income	132	506	1,225	2,192
Profit before tax	**5,160**	**4,895**	**19,098**	**19,358**
Income tax expense	(328)	(426)	(1,290)	(2,017)
Profit for the period before MDET and once-off charges	**4,832**	**4,469**	**17,808**	**17,341**
Once-off charges			(8,187)	
Tax credit on once-off charges			716	
Medical device excise tax (MDET)	(191)		(691)	
Profit for the period after MDET and once-off charges	**4,641**	**4,469**	**9,646**	**17,341**
Earnings per ADR (US cents)	20.8	20.8	44.0	81.0
Diluted earnings per ADR (US cents)	19.2	19.8	41.2	77.3
Earnings per ADR excluding MDET and once-off charges (US cents)	21.7	20.8	81.2	81.0
Diluted earnings per ADR excluding MDET and once-off charges (US cents)	20.0	19.8	76.0	77.3
	22,261,568	21,476,973	21,936,647	21,418,821

Weighted average no. of ADRs used in computing basic earnings per ADR				
Weighted average no. of ADRs used in computing diluted earnings per ADR	24,218,493	22,563,207	23,428,174	22,443,404

Trinity Biotech plc

Consolidated Balance Sheets

	Dec 31, 2013 US$ 000 (unaudited)	Sept 30, 2013 US$ 000 (unaudited)	Dec 31, 2012 US$ 000 (audited)
ASSETS			
Non-current assets			
Property, plant and equipment	12,991	12,090	8,883
Goodwill and intangible assets	128,547	126,324	73,046
Deferred tax assets	7,044	5,935	4,073
Other assets	1,162	1,011	908
Total non-current assets	149,744	145,360	86,910
Current assets			
Inventories	29,670	27,387	20,757
Trade and other receivables	24,268	23,119	14,457
Income tax receivable	487	208	336
Cash and cash equivalents	22,317	26,806	74,947
Total current assets	76,742	77,520	110,497
TOTAL ASSETS	226,486	222,880	197,407
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the parent			
Share capital	1,182	1,169	1,134
Share premium	8,732	7,006	5,138
Accumulated surplus	168,772	163,039	158,973
Other reserves	4,325	3,916	4,135
Total equity	183,011	175,130	169,380
Current liabilities			
Income tax payable	770	1,347	1,092
Trade and other payables	20,131	21,587	11,824
Provisions	75	50	50
Total current liabilities	20,976	22,984	12,966
Non-current liabilities			
Other payables	4,596	5,959	4,318

Deferred tax liabilities	17,903	18,807	10,743
Total non-current liabilities	22,499	24,766	15,061
TOTAL LIABILITIES	43,475	47,750	28,027
TOTAL EQUITY AND LIABILITIES	226,486	222,880	197,407

Trinity Biotech plc

Consolidated Statement of Cash Flows

(US$000 s)	**Three Months Ended Dec 31, 2013**	**Three Months Ended Dec 31, 2012**	**Year Ended Dec 31, 2013**	**Year Ended Dec 31, 2012**
	(unaudited)	**(unaudited)**	**(unaudited)**	**(unaudited)**
Cash and cash equivalents at beginning of period	**26,806**	**74,455**	**74,947**	**71,085**
Operating cash flows before changes in working capital	3,877	5,973	19,764	22,285
Changes in working capital	(915)	(81)	(8,657)	(3,367)
Cash generated from operations	2,962	5,892	11,107	18,918
Net Interest and Income taxes received/(paid)	(74)	83	599	1,138
Capital Expenditure & Financing (net)	(5,015)	(4,236)	(19,583)	(12,920)
Free cash flow	(2,127)	1,739	(7,877)	7,136
Proceeds from sale of Coagulation product line				11,250
Cash paid to acquire Fiomi Diagnostics and Phoenix Biotech				(5,957)
Cash paid to acquire Immco and Blood Bank Screening Business			(39,424)	
Payments for licence fees	(2,362)		(2,362)	
Net cash acquired on acquisition			1,406	
Dividend payment			(4,373)	(3,223)
Repurchase of own company shares		(1,247)		(5,344)
Cash and cash equivalents at end of period	**22,317**	**74,947**	**22,317**	**74,947**

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: March 4, 2014.