TRINITY BIOTECH PLC
Form 6-K
March 04, 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 March, 2015

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 3, 2015

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Trinity Biotech Announces Results for Q4 and Fiscal Year 2014.

2014 Revenues grow by 15%.

DUBLIN, Ireland (March 3, 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 fiscal year 2014 and the quarter ended December 31, 2014.

Fiscal year 2014 Results

Total revenues for fiscal year 2014 were $104.9m versus $91.2m in 2013, an increase of 15.0% year on year.

Point-of-care revenues increased from $19.8m in 2013 to $20.0m in 2014, which represents an increase of 1.4%.

Meanwhile, Clinical Laboratory revenues grew by almost 19%, mainly due to:

- higher diabetes revenues achieved through a combination of higher placements of Premier instruments and the increased pull through of related consumables for the larger installed base; and
- the underlying growth and full year impact of the Immco and blood bank screening acquisitions which were made during 2013.

Growth in these areas was partly offset by lower Lyme revenues. This decrease was attributable to the impact of adverse weather conditions in Q1, 2014 which impacted the prevalence of Lyme disease in subsequent months.

Revenues for Q4 and fiscal year 2014 by key product area were as follows:

	2013 Quarter 4 US$ 000	2014 Quarter 4 US$ 000	Q4 2014 vs Q4 2013 %	Full Year 2013 US$ 000	Full Year 2014 US$ 000	Full Year 2014 vs 2013 %
Point-of-Care	5,088	5,451	7.1%	19,754	20,036	1.4%
Clinical Laboratory	20,367	21,229	4.2%	71,462	84,835	18.7%
Total	**25,455**	**26,680**	**4.8%**	**91,216**	**104,871**	**15.0%**

The other key financial results for 2014 were as follows:

Operating profit for the year grew by 5.0% from $17.2m to $18.0m. This represents an operating margin of 17.2%.

Profit after tax increased from $17.1m to $17.2m.

EBITDA before share option expense for the year increased from $22.8m to $23.8m

EPS for the year was 76 cents versus 78 cents in 2013 whilst diluted EPS was 73 cents (2013: 73 cents).

The tax charge for the year was 4.7% which compares favourably to the 7.0% reported in 2013. This low effective rate of tax is due to the competitive corporation tax rate in Ireland and the availability of R&D tax credits in a number of jurisdictions.

The growth in profits was achieved despite the impact of a number of factors which had an adverse impact on profitability during the year, including:

the impact of the operational costs and closure costs associated with two facilities which were undertaken as part of the blood banking acquisition. The closure of these facilities and associated costs occurred in Q3, 2014;

sales and marketing costs incurred in relation to the company s new Meritas range for which there were no matching revenues during the year;

increased sales of Premier instruments instrument sales by their nature have lower margins; and

lower sales of Lyme products which typically attract stronger gross margins.

Quarter 4 Results

Total revenues for Q4, 2014 were $26.7m which compares to $25.5m in Q4, 2013, an increase of 5%. Excluding the impact of exchange rate movements due to the strengthening dollar, the increase would have been 6.4%.

Point-of-Care revenues for Q4, 2014 increased by over 7% versus Q4, 2013. This increase reflects stronger sales of HIV products in Africa in the quarter.

Clinical Laboratory revenues increased from $20.4m to $21.2m, an increase of over 4% compared to Q4, 2013, or 6.2% after the exclusion of exchange rate movements. The main drivers of this growth were the continued strong performance of Premier and increased autoimmune sales (Immco) particularly with respect to Sjögren s disease testing.

Consistent with the previous quarters in 2014, the gross margin of 47.5% for the quarter was lower than the equivalent quarter in 2013 due to the impact of increased Premier instrument sales and lower Lyme sales.

Research and Development expenses were just under $1m, which was broadly consistent with the corresponding period last year. Selling, General and Administrative (SG&A) expenses increased, from $6.5m to $7.2m which includes increased Meritas related expenditure, reflecting the addition of a new dedicated sales and marketing team.

The impact of the lower gross margin and increased SG&A expenditure has resulted in a reduction in operating profit from $4.8m to $4.3m. Meanwhile, profit after tax for the quarter was $4.1m, which represents an EPS for the quarter of 18 cents. EBITDA before share option expense for the quarter was $5.8m.

Cardiac Update

Trinity achieved some key milestones during 2014 relating to our new point-of-care cardiac products on the Meritas platform. CE marking was obtained for the company s new high sensitivity Troponin I test in Q1, 2014. The trial data as part of these trials demonstrated unrivalled performance for a point-of-care Troponin product. These results were subsequently corroborated by an independent trial carried out at Hennepin County Medical Centre, Minneapolis and published at the AACC meeting in July 2014.

FDA clinical trials for the product commenced in Q2, 2014 with enrolment initially taking place at 5 trial sites throughout the USA. Due to the impact of a format change in a chemical raw material used in the product, these clinical trials were temporarily suspended in October, 2014. After taking remedial action, the product s performance was restored and the resumption of trials was announced in February, 2015. Enrolment is now taking place at 12 sites in the USA with the entire trial process, consisting of patient sampling, data collection, cardiologist adjudication and statistical analysis, expected to be completed by the end of July, 2015 with FDA submission planned for August, 2015.

Significant progress was also made on the second test to be launched on the Meritas platform, BNP, which determines the risk of heart failure. CE Marking for this product was obtained in Q3, 2014 with FDA submission to follow in 2015. As with our Troponin I test, we are extremely confident that this product will obtain FDA approval based on its strong performance in trials to date.

Premier Update

It was another strong year for our Premier diabetes instrument. We shipped a record number of instruments and achieved our target of 460 placements in 2014. Sales were strong in a wide range of markets including the USA, Europe, China, and South-East Asia. In addition, we gained access to the Brazilian market which performed very strongly throughout 2014 with placements in this single market reaching 121 instruments.

During 2014, Trinity also launched the Premier Resolution instrument which has been specifically designed for the detection and identification of haemoglobin variants as opposed to A1c testing which is currently undertaken by the existing Premier instrument. Premier Resolution will act as a companion instrument for the Premier and will provide greater access to the variant segment of the market.

CLIA waiver for Rapid Syphilis test

In December, 2014 a CLIA waiver was awarded by the FDA in relation to the Syphilis Health Check test, the first ever waiver for a rapid screening test for syphilis in the United States. Importantly, the waiver allows the test to be performed by untrained healthcare workers in a variety of non-traditional sites such as emergency rooms, public health department clinics and other free standing counselling and testing locations.

In recent years the incidence of syphilis in the USA has been growing at a significant rate. Given that this is the only product which is capable of reaching the principal patient demographic at the point-of-care this represents a key growth opportunity for Trinity. It will also serve as a companion product for our Uni-Gold rapid HIV test which itself is CLIA waived and services a similar patient demographic.

Comments

Commenting on the results, Kevin Tansley, Chief Financial Officer, said Overall revenues in 2014 increased by 15% to $104.9m. This increase was driven by particularly strong growth for our Premier business and higher Immco revenues. Meanwhile, operating profit for the year grew to over $18m. Whilst overall profit after tax increased moderately, this was achieved in the context of increased expenditure on our new cardiac sales force and the impact that the combination of higher instrument and lower Lyme sales had on gross margins.

Ronan O Caoimh, CEO of Trinity said During the year :

We achieved CE marking for our high sensitivity Troponin I product and commenced the clinical trials for FDA approval. Whilst these trials were temporarily suspended in October 2014, we were happy to be able to announce the resumption of the trials in February, 2015 at 12 trial sites with the result that we expect to be in a position to submit the trial data to the FDA in August of this year;

Our Premier instrument had another excellent year with a record 460 instruments being placed during the year. The highlight was the success achieved by our Brazilian sales force who placed 121 Premier instruments in the 11 months following regulatory approval. After three short years post-launch we have already placed close to 1,000 Premier instruments worldwide;

We now have the only rapid syphilis test which is CLIA waived in the USA, thus allowing point-of-care syphilis testing to be carried out in the public health market. Given the increasing incidence of syphilis in the USA and the fact that we have the only approved test in the market, this is clearly a very significant growth opportunity for us. This belief has been reinforced by the across the board interest expressed by state and city public health departments since the CLIA waiver was awarded in December 2014; and

We successfully completed the integration of the Immco and blood bank screening acquisitions and were particularly pleased with the success of our new Sjögren s test following its nationwide launch across the USA.

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 Dec 31, 2014	Three Months Ended Dec 31, 2013	Year Ended Dec 31, 2014	Year Ended Dec 31, 2013
(US$000 s except share data)	**(unaudited)**	**(unaudited)**	**(unaudited)**	**(unaudited)**
Revenues	**26,680**	**25,455**	**104,871**	**91,216**
Cost of sales	(14,014)	(12,828)	(54,524)	(45,996)
Gross profit	**12,666**	**12,627**	**50,347**	**45,220**
Gross profit %	*47.5%*	*49.6%*	*48.0%*	*49.6%*
Other operating income	85	247	424	532
Research & development expenses	(961)	(1,035)	(4,290)	(3,691)
Selling, general and administrative expenses	(7,238)	(6,481)	(26,964)	(22,901)
Indirect share based payments	(255)	(521)	(1,478)	(1,978)
Operating profit	**4,297**	**4,837**	**18,039**	**17,182**
Financial income	48	132	96	1,300
Financial expenses	(34)		(69)	(75)
Net financing income	14	132	27	1,225
Profit before tax	**4,311**	**4,969**	**18,066**	**18,407**
Income tax expense	(187)	(328)	(853)	(1,290)
Profit for the period before once-off charges	**4,124**	**4,641**	**17,213**	**17,117**
Once-off charges				(8,187)
Tax credit on once-off charges				716
Profit for the period after once-off charges	**4,124**	**4,641**	**17,213**	**9,646**
Earnings per ADR (US cents)	18.0	20.8	75.7	44.0
Diluted earnings per ADR (US cents)	17.6	19.2	72.6	41.2
Earnings per ADR excluding once-off charges (US cents)	18.0	20.8	75.7	78.0
Diluted earnings per ADR excluding once-off	17.6	19.2	72.6	73.1

charges (US cents)

Weighted average no. of ADRs used in computing basic earnings per ADR	22,916,417	22,261,568	22,749,726	21,936,647
Weighted average no. of ADRs used in computing diluted earnings per ADR	23,482,268	24,218,493	23,717,747	23,428,174

Trinity Biotech plc

Consolidated Balance Sheets

	Dec 31, 2014 US$ 000 (unaudited)	Sept 30, 2014 US$ 000 (unaudited)	Dec 31, 2013 US$ 000 (unaudited)
ASSETS			
Non-current assets			
Property, plant and equipment	17,877	15,782	12,991
Goodwill and intangible assets	145,024	141,815	128,547
Deferred tax assets	9,798	10,066	7,044
Other assets	1,091	1,276	1,162
Total non-current assets	173,790	168,939	149,744
Current assets			
Inventories	33,517	33,779	29,670
Trade and other receivables	26,080	25,190	24,268
Income tax receivable	351	139	487
Cash and cash equivalents	9,102	8,949	22,317
Total current assets	69,050	68,057	76,742
TOTAL ASSETS	242,840	236,996	226,486
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the parent			
Share capital	1,204	1,203	1,182
Share premium	12,422	12,295	8,732
Accumulated surplus	183,375	178,960	168,772
Other reserves	(26)	2,321	4,325
Total equity	196,975	194,779	183,011
Current liabilities			
Income tax payable	785	555	770
Trade and other payables	21,196	15,151	20,131
Provisions	75	75	75
Total current liabilities	22,056	15,781	20,976
Non-current liabilities			
Other payables	2,370	4,676	4,596

Deferred tax liabilities	21,439	21,760	17,903
Total non-current liabilities	23,809	26,436	22,499
TOTAL LIABILITIES	45,865	42,217	43,475
TOTAL EQUITY AND LIABILITIES	242,840	236,996	226,486

Trinity Biotech plc

Consolidated Statement of Cash Flows

(US$000 s)	**Three Months Ended Dec 31, 2014** **(unaudited)**	**Three Months Ended Dec 31, 2013** **(unaudited)**	**Year Ended Dec 31, 2014** **(unaudited)**	**Year Ended Dec 31, 2013** **(unaudited)**
Cash and cash equivalents at beginning of period	**8,949**	**26,806**	**22,317**	**74,947**
Operating cash flows before changes in working capital	5,048	3,877	22,027	19,764
Changes in working capital	3,596	(915)	(6,512)	(8,657)
Cash generated from operations	8,644	2,962	15,515	11,107
Net Interest and Income taxes received/(paid)	(53)	(74)	237	599
Capital Expenditure & Financing (net)	(8,438)	(5,015)	(23,937)	(19,583)
Free cash flow	153	(2,127)	(8,185)	(7,877)
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			(5,030)	(4,373)
Cash and cash equivalents at end of period	**9,102**	**22,317**	**9,102**	**22,317**

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 3, 2015.