TRINITY BIOTECH PLC
Form 6-K
July 22, 2016

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, 2016

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 21, 2016

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Trinity Biotech Announces Quarter 2 Financial Results

DUBLIN, Ireland (July 21, 2016) . 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, 2016.

Quarter 2 Results

Total revenues for Q2, 2016 were $26.3m compared to $24.3m in Q2, 2015 which is an increase of 8%. However, when the impact of foreign exchange movements, due to the strength of the US dollar against a range of other currencies, is removed revenues would have been $26.6m this quarter, thus representing an increase of 10%.

Point-of-Care revenues for Q2, 2016 were $4.8m, which represents an increase of $1.4m or 41% compared with the same quarter last year. This increase was due to higher sales of HIV kits in Africa.

Clinical Laboratory revenues for the quarter were $21.5m. However, on a constant currency basis revenues would have been $21.8m compared to $20.9m in Q2, 2015, an increase of 5%. This increase was principally due to higher sales of diabetes and autoimmune products.

Revenues for Q2, 2016 by key product area were as follows:

	2015 Quarter 2 US$ 000	**2016 Quarter 2 US$ 000**	**2016 Quarter 2 FX adjusted* US$ 000**	**Increase/ (decrease) %**
Point-of-Care	3,371	4,786	4,769	*41.5%*
Clinical Laboratory	20,886	21,502	21,844	*4.6%*
Total	***24,257***	***26,288***	***26,613***	***9.7%***

* *quarter 2, 2016 revenues have been recalculated on a constant currency basis using the exchange rates prevailing in Q2, 2015*

Gross profit for Q2, 2016 amounted to $11.8m, representing a gross margin of 45.0%. Whilst this is lower than the 47.0% achieved in Q2, 2015, it does represent an improvement on the 43.1% reported in Q1 of this year and this is mainly attributable to the impact of higher margin HIV revenues.

Research and Development expenses have remained consistent with the equivalent quarter last year at $1.3m. Meanwhile, Selling, General and Administrative (SG&A) expenses have increased over the same period from $6.7m to $7.8m. This increase is due to the combination of foreign exchange rate factors and increased discretionary sales and marketing expenditure which includes pre-launch cardiac costs.

The net financing expense for the quarter was $121,000 versus $98,000 in the equivalent quarter in 2015. This expense can be broken down into its component parts as follows:

Net financing expense	**Q2 2016 US$ 000**	**Q2 2015 US$ 000**
Financial income	**223**	**93**
Financial expense Exchangeable note	(1,150)	(1,134)
Other financial expenses	(35)	(35)
	(1,185)	**(1,169)**
Non-cash financial income	1,020	1,150
Non-cash financial expense accretion interest	(179)	(172)
	841	**978**
Net financial expense	**(121)**	**(98)**

Financial income increased to $223,000 from $93,000 in the equivalent quarter last year. This was primarily due to improved interest rates and a different time profile of deposits.

Financial expenses primarily consist of the cash interest payable on the Company s exchangeable notes, which is $1.15m per quarter. The equivalent expense in 2015 is slightly lower than this due to the fact that the note offering closed on April 9, 2015 and so a full quarter of interest was not incurred.

Non-cash financial income represents adjustments required to the fair value of the derivatives embedded in the exchangeable notes along with an amount to accrete the fair value of the debt liability back to its nominal value ($115 million) over the term of the debt using an effective interest rate methodology. For Q2, 2016, the fair value adjustment was a gain to the income statement of $1m.

The tax charge for Q2, 2016 was $0.1m which equates to an effective tax rate of approximately 6% and is broadly in line with the effective rate of 7% in Q2, 2015.

Profit before tax for the quarter was $2.2m compared to $2.9m in Q2, 2015. Meanwhile, profit after tax for the quarter was $2.1m versus $2.7m for the comparative quarter. EPS for the quarter was 9.1 cents which compares to 11.6 cents for the equivalent period last year. The fully diluted EPS for the quarter was 8.5 cents.

Earnings before interest, tax, depreciation, amortisation and share option expense for the quarter was $4.4m.

Cardiac Update

In December, 2015 Trinity submitted a 510(k) application for its Meritas Troponin I Test and the Meritas Point-of-Care Analyzer to the FDA. The FDA s review of the application is proceeding according to our expectations. As previously announced, as part of this review process, additional clinical data were requested, and this clinical work will be completed within the next two weeks enabling us to provide a response to the FDA during August, 2016.

The US clinical validation studies in support of a 510(k) submission to the US FDA for a second cardiac marker assay, B-type Natriuretic Protein (BNP), are progressing well. There are 10 clinical sites, across the US, that have been actively enrolling patient samples. Overall enrolment is currently at 90% of study target, with completion of enrolment anticipated by the end of July, 2016. We are anticipating submission of our BNP 510(k) application to the FDA by the end of Q3, 2016.

Share Buyback

The Company announced the commencement of a share repurchase program in March, 2016. During the quarter, the Company repurchased 406,000 ADRs at an average price of $11.14, representing a total value of $4.5m.

For the year to date, the Company has repurchased 538,000 ADRs, at an average price of $11.20. The total spent on share repurchases for the year to date has been $6.0m.

Comments

Commenting on the results, Kevin Tansley, Chief Financial Officer, said Operating profit for the quarter was $2.4m. This was lower than that achieved in Q2, 2015 partly due to tighter gross margins which is partly due to the impact of exchange rate movements. In addition we are seeing the impact of higher indirect costs again due to exchange rate factors as well as higher sales and marketing costs. However, when compared to Q1 this year, operating profits and EPS have increased by approximately 30%, with the key factor being the growth in revenues this quarter.

Ronan O Caoimh, CEO, stated We were very pleased with the revenue growth of 10% achieved this quarter. This was due to higher HIV sales in Africa and strong growth in our diabetes and autoimmune product lines.

In terms of our cardiac products we have made very significant progress. We have almost completed the patient enrolment to support the additional data requested by the FDA following its initial review of our Troponin submission. This data will form part of a full and comprehensive response document, which will be submitted to the FDA in August, in order to address all of its queries. Meanwhile, we are on the verge of completing our clinical trials for our BNP product and remain on target to make our 510(k) submission to the FDA by the end of Q3, 2016. Both of these products are key to our strategic development and we are very pleased to be reaching these regulatory milestones on the road to obtaining FDA approvals.

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, 2016** **(unaudited)**	**Three Months Ended June 30, 2015** **(unaudited)**	**Six Months Ended June 30, 2016** **(unaudited)**	**Six Months Ended June 30, 2015** **(unaudited)**
Revenues	**26,288**	**24,257**	**49,804**	**49,267**
Cost of sales	(14,472)	(12,864)	(27,856)	(25,869)
Gross profit	**11,816**	**11,393**	**21,948**	**23,398**
Gross profit%	*45.0%*	*47.0%*	*44.1%*	*47.5%*
Other operating income	72	72	141	150
Research & development expenses	(1,267)	(1,269)	(2,414)	(2,267)
Selling, general and administrative expenses	(7,797)	(6,713)	(14,758)	(12,905)
Indirect share based payments	(468)	(473)	(735)	(1,031)
Operating profit	**2,356**	**3,010**	**4,182**	**7,345**
Financial income	223	93	443	94
Financial expenses	(1,185)	(1,169)	(2,366)	(1,193)
Non-cash financial income	841	978	(1,188)	978
Net financing expense	(121)	(98)	(3,111)	(121)
Profit before tax	**2,235**	**2,912**	**1,071**	**7,224**
Income tax expense	(131)	(218)	(313)	(522)
Profit for the period	**2,104**	**2,694**	**758**	**6,702**
Earnings per ADR (US cents)	9.1	11.6	3.3	29.0
Earnings per ADR excluding non-cash financial income (US cents)	5.5	7.4	8.4	24.8
Diluted earnings per ADR (US cents)	8.5	9.9	14.9*	26.1
Weighted average no. of ADRs used in computing basic earnings per ADR	23,016,169	23,195,016	23,152,018	23,090,704
Weighted average no. of ADRs used in computing diluted earnings per ADR	28,409,024	28,812,187	28,526,486	26,285,071

* Under IAS 33 *Earnings per Share*, diluted earnings per share cannot be anti-dilutive. Therefore, diluted earnings per ADR in accordance with IFRS would be 3.3 cents (i.e. equal to basic earnings per ADR).

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, 2016 US$ 000 (unaudited)	March 31, 2016 US$ 000 (unaudited)	Dec 31, 2015 US$ 000 (audited)
ASSETS			
Non-current assets			
Property, plant and equipment	21,760	21,460	20,659
Goodwill and intangible assets	169,049	165,157	161,324
Deferred tax assets	13,312	13,096	12,792
Other assets	932	860	954
Total non-current assets	205,053	200,573	195,729
Current assets			
Inventories	39,253	35,709	35,125
Trade and other receivables	27,832	26,260	25,602
Income tax receivable	712	664	550
Cash and cash equivalents	84,920	96,829	101,953
Total current assets	152,717	159,462	163,230
TOTAL ASSETS	357,770	360,035	358,959
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the parent			
Share capital	1,221	1,220	1,220
Share premium	15,575	15,521	15,526
Accumulated surplus	197,588	199,453	201,951
Other reserves	(3,721)	(3,723)	(4,809)
Total equity	210,663	212,471	213,888
Current liabilities			
Income tax payable	657	1,026	1,163
Trade and other payables	19,384	19,195	18,874
Provisions	75	75	75
Total current liabilities	20,116	20,296	20,112
Non-current liabilities			
Exchangeable senior note payable	99,232	100,073	98,044

Other payables	1,986	2,057	2,096
Deferred tax liabilities	25,773	25,138	24,819
Total non-current liabilities	126,991	127,268	124,959
TOTAL LIABILITIES	147,107	147,564	145,071
TOTAL EQUITY AND LIABILITIES	357,770	360,035	358,959

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, 2016** **(unaudited)**	**Three Months Ended June 30, 2015** **(unaudited)**	**Six Months Ended June 30, 2016** **(unaudited)**	**Six Months Ended June 30, 2015** **(unaudited)**
Cash and cash equivalents at beginning of period	**96,829**	**5,744**	**101,953**	**9,102**
Operating cash flows before changes in working capital	5,282	4,130	7,786	10,428
Changes in working capital	(3,234)	(2,906)	(3,862)	(7,225)
Cash generated from operations	2,048	1,224	3,924	3,203
Net Interest and Income taxes (paid)/received	149	(223)	(92)	(332)
Capital Expenditure & Financing (net)	(5,995)	(7,218)	(11,427)	(11,334)
Free cash flow	(3,798)	(6,217)	(7,595)	(8,463)
Share buyback	(4,699)		(6,026)	
Payment of HIV-2 licence fee	(1,112)		(1,112)	(1,112)
30 year Convertible Note interest payment	(2,300)		(2,300)	
30 year Convertible Note proceeds, net of fees		110,730		110,730
Cash and cash equivalents at end of period	**84,920**	**110,257**	**84,920**	**110,257**

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 22, 2016.