TRINITY BIOTECH PLC
Form 6-K
October 26, 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 October, 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 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

If Yes is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-_____

Press Release dated October 25, 2016

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Trinity Biotech announces Quarter 3 Financial Results

DUBLIN, Ireland (October 25, 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 September 30, 2016.

Quarter 3 Results

Total revenues for Q3, 2016 were $26.1m which compares to $25.8m in Q3, 2015, an increase of 1.4%.

Point-of-Care revenues for Q3, 2016 decreased from $5.4m to $4.9m when compared to Q3, 2015, a decline of 9.5%. This is within the normal quarterly fluctuation range of HIV sales in Africa.

Clinical Laboratory revenues increased to $21.2m, which represents an increase of 4.3% compared to Q3, 2015. This increase was primarily attributable to increased Premier and autoimmune revenues.

Unlike in previous quarters, the impact of foreign exchange on revenues was not significant when compared to the equivalent quarter last year. When calculated, its impact was to reduce this quarter s revenues by less than 0.5% with the weakness in Sterling being the biggest single factor.

Revenues for Q3, 2016 were as follows:

	2015 Quarter 3 US$ 000	**2016 Quarter 3 US$ 000**	**Increase/ (decrease) %**
Point-of-Care	5,418	4,903	*(9.5%)*
Clinical Laboratory	20,343	21,224	*4.3%*
Total	***25,761***	***26,127***	***1.4%***

Gross profit for Q3, 2016 amounted to $11.7m representing a gross margin of 44.7%, which is lower than the 46.5% achieved in Q3, 2015. This decrease is largely due to lower sales of higher margin point-of-care products and the knock-on impact of past currency movements primarily the impact of the stronger dollar on distributor pricing.

Research and Development expenses have remained in line with the equivalent quarter last year at $1.3m. Meanwhile, Selling, General and Administrative (SG&A) expenses have remained at $7.5m for the quarter.

Operating profit for the quarter was $2.7m, which is lower than the $3.0m achieved in Q3, 2015, and this is attributable to the impact of higher revenues and lower indirect costs being more than offset by the lower gross

margin.

The net financing expense for the quarter was $3.1m versus income of $9.6m in the equivalent quarter of 2015. This financing income/expense can be broken down into its component parts as follows:

Net financing income /(expense)	**Q3 2016 US$ 000**	**Q3 2015 US$ 000**
Financial income	**212**	**204**
Financial expense Exchangeable note	(1,150)	(1,064)
Other financial expenses	(29)	(21)
Financial expense (cash)	**(1,179)**	**(1,085)**
Non-cash financial income / (expense)	(1,940)	10,720
Non-cash financial expense accretion interest	(180)	(208)
Non-cash financial income / (expense)	**(2,120)**	**10,512**
Net financial income / (expense)	**(3,087)**	**9,631**

Financial income increased to $212,000 from $204,000 in the equivalent quarter last year. This was primarily due to improved interest rates.

Financial expenses primarily consist of the cash interest payable on the company s Exchangeable Notes, which amounts to $1.15m per quarter.

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 Q3, 2016, the fair value adjustment to the value of the embedded derivatives was a charge to the income statement of $1.9m.

The loss before tax for the period was $0.4m, though this was largely impacted by non-cash charges related to the Exchangeable Notes. Excluding these non-cash items, the profit before tax for the quarter was $1.8m.

The tax charge for Q3, 2016 was $0.1m, an effective tax rate of 8.5% on the profit for the quarter excluding non-cash charges.

The loss after tax for the period was $0.5m. However, excluding the non-cash elements of the Exchangeable Notes, this would have been a profit of $1.6m, which equates to an adjusted EPS of 7.0 cents. This compares to $1.8m and an adjusted EPS of 7.5 cents in Q3, 2015. Diluted EPS for the quarter amounted to 9.7 cents, which is consistent with the equivalent quarter in 2015.

The above results do not reflect the impact of the decisions to withdraw the Meritas Troponin submission from the FDA and to close the company s facility in Uppsala, Sweden as both of these events occurred after the quarter end. It is expected that the company will record an impairment charge of in excess of $50m in relation to the costs incurred on the Meritas project as well as a provision for closure costs associated with the Swedish facility. Both of these will be reflected in the company s Q4 income statement.

Cash generated from operations during the quarter was $5.6m, though this was offset by capital expenditure of $5.6m and interest and tax payments of $0.2m, resulting in a net cash outflow for the quarter of under $0.2m. This resulted in a cash balance at the end of the quarter of $84.8m.

Earnings before interest, tax, depreciation, amortisation and share option expense for the quarter was $4.6m.

Meritas withdrawal of FDA submission

On October 4, 2016 Trinity Biotech announced that it was withdrawing its 510(k) premarket notification submission for the Meritas Troponin-I Test and Meritas Point-of-Care Analyzer. This followed a meeting with the FDA, where they asked Trinity to consider withdrawing its submission due to their concerns about clinical performance. These concerns focussed on the analyzer s operating temperature range and the inconsistency of the test s performance with the most recently cleared laboratory Troponin test.

Given these concerns, the company decided to withdraw the submission and to cease development of its Troponin product for the U.S. market. It was felt that, even after carrying out additional development work on the product, which would be both lengthy and likely to cost an additional $20-30m, there was insufficient certainty that its performance could ever match a recently approved laboratory Troponin test. As a consequence of this, the company also decided not to submit its Meritas BNP test for heart failure to the FDA, as this was being developed as a sister product for Troponin.

The Meritas platform has many potential applications in the point-of-care arena, and thus the company has embarked on an internal review process to determine the best future opportunity for this technically excellent platform. This process is expected to take between 9 and 12 months. In conjunction with this, the Company will close its facility in Uppsala, Sweden and transfer the technology to its headquarters in Bray, Ireland.

In its Q4 income statement, the company expects to recognise an impairment charge in excess of $50m reflecting the costs incurred on the Meritas platform to date plus an additional provision for closure costs in relation to the Swedish facility.

Comments

Commenting on the results, Kevin Tansley, Chief Financial Officer, said Operating profit this quarter was $2.7m, which whilst lower than the equivalent quarter last year, did represent an improvement compared to our more recent quarters. This was driven by improved top line performance. Whilst our gross margin remains under pressure, mainly due to product mix and carry over currency factors, higher revenues combined with control over indirect costs has resulted in an operating margin of over 10%. Meanwhile, our diluted EPS for the quarter remained consistent at 9.7 cents per ADR.

Ronan O Caoimh, CEO of Trinity said The last few weeks have been difficult for the company. We had invested considerable time and effort in developing our Troponin test on the Meritas platform and it was extremely frustrating that, even with its clear performance advantages over its competitors, FDA approval was not forthcoming. Following this we have taken decisive action. We are closing our facility in Sweden, resulting in 40 redundancies and transferring the technology to our Bray facility. Once all closure costs have been incurred, this will result in a reduction in expenditure on the platform from $9m p.a. to $1.5m p.a. thus returning the company to a near break-even cash flow position. We also believe that the excellent technical performance of Meritas still makes this a valuable platform. In the months ahead we will look closely at a wide range of alternatives with a view to maximising this value. This will include looking at alternative menus and/or collaborations with third parties.

In the meantime, we will focus on expanding our core business which has a number of growth drivers. In particular, we will continue to place large numbers of Premier instruments in an ever increasing number of countries, thus building market share. We will also increase our penetration of the haemoglobin variant market with our newly launched Premier Resolution instrument. We will continue to grow our autoimmune business, building on our growth of product sales and reference laboratory services. We are also determined to expand our HIV franchise in Africa. Having already conquered the confirmatory market, we will now look to enter the higher volume screening market.

Whilst we will continue to look for highly synergistic and earnings accretive acquisitions, I believe that at our current share price, buying back our own shares represents the best deployment of capital at this juncture. This, coupled with the growth opportunities inherent in our existing business, will enhance our earnings capacity and drive shareholder value .

Forward-looking statements in this release are made pursuant to the safe harbor provision of the Private Securities 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 September 30, 2016 (unaudited)**	**Three Months Ended September 30, 2015 (unaudited)**	**Nine Months Ended September 30, 2016 (unaudited)**	**Nine Months Ended September 30, 2015 (unaudited)**
Revenues	**26,127**	**25,761**	**75,931**	**75,258**
Cost of sales	(14,460)	(13,776)	(42,316)	(39,780)
Gross profit	**11,667**	**11,985**	**33,615**	**35,478**
Gross profit %	*44.7%*	*46.5%*	*44.3%*	*47.1%*
Other operating income	70	73	211	222
Research & development expenses	(1,296)	(1,293)	(3,711)	(3,560)
Selling, general and administrative expenses	(7,487)	(7,467)	(22,245)	(20,467)
Indirect share based payments	(236)	(327)	(971)	(1,357)
Operating profit	**2,718**	**2,971**	**6,899**	**10,316**
Financial income	212	204	657	299
Financial expenses	(1,179)	(1,085)	(3,545)	(2,279)
Non-cash financial income / (expense)	(2,120)	10,512	(3,308)	11,490
Net financing income / (expense)	(3,087)	9,631	(6,196)	9,510
Profit / (loss) before tax	**(369)**	**12,602**	**703**	**19,826**
Income tax expense	(148)	(339)	(462)	(858)
Profit / (loss) for the period	**(517)**	**12,263**	**241**	**18,968**
Earnings per ADR (US cents)	(2.3)	52.9	1.0	82.0
Earnings per ADR excluding non-cash financial income (US cents)	7.0	7.5	15.4	32.3
Diluted earnings per ADR (US cents)	9.7*	9.7	24.6*	35.7
Weighted average no. of ADRs used in computing basic earnings per ADR	22,797,208	23,202,228	23,032,885	23,128,287
Weighted average no. of ADRs used in computing diluted earnings per ADR	28,379,444	28,766,691	28,452,580	27,059,058

*

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 1.0 cents for the year to date, and a loss of 2.3 cents for the quarter (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

	September 30, 2016 US$ 000 (unaudited)	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	21,495	21,760	21,460	20,659
Goodwill and intangible assets	173,240	169,049	165,157	161,324
Deferred tax assets	13,531	13,312	13,096	12,792
Other assets	849	932	860	954
Total non-current assets	209,115	205,053	200,573	195,729
Current assets				
Inventories	39,989	39,253	35,709	35,125
Trade and other receivables	25,802	27,832	26,260	25,602
Income tax receivable	811	712	664	550
Cash and cash equivalents	84,751	84,920	96,829	101,953
Total current assets	151,353	152,717	159,462	163,230
TOTAL ASSETS	360,468	357,770	360,035	358,959
EQUITY AND LIABILITIES				
Equity attributable to the equity holders of the parent				
Share capital	1,222	1,221	1,220	1,220
Share premium	15,801	15,575	15,521	15,526
Accumulated surplus	197,379	197,588	199,453	201,951
Other reserves	(4,002)	(3,721)	(3,723)	(4,809)
Total equity	210,400	210,663	212,471	213,888
Current liabilities				
Income tax payable	772	657	1,026	1,163
Trade and other payables	19,976	19,384	19,195	18,874
Provisions	75	75	75	75
Total current liabilities	20,823	20,116	20,296	20,112
Non-current liabilities				
Exchangeable senior note payable	101,351	99,232	100,073	98,044

Other payables	1,939	1,986	2,057	2,096
Deferred tax liabilities	25,955	25,773	25,138	24,819
Total non-current liabilities	129,245	126,991	127,268	124,959
TOTAL LIABILITIES	150,068	147,107	147,564	145,071
TOTAL EQUITY AND LIABILITIES	360,468	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 September 30, 2016 (unaudited)**	**Three Months Ended September 30, 2015 (unaudited)**	**Nine Months Ended September 30, 2016 (unaudited)**	**Nine Months Ended September 30, 2015 (unaudited)**
Cash and cash equivalents at beginning of period	**84,920**	**110,257**	**101,953**	**9,102**
Operating cash flows before changes in working capital	5,164	3,851	12,950	14,279
Changes in working capital	393	(166)	(3,469)	(8,504)
Cash generated from operations	5,557	3,685	9,481	5,775
Net Interest and Income taxes paid	(171)	(108)	(263)	(440)
Capital Expenditure & Financing (net)	(5,555)	(4,290)	(16,982)	(15,623)
Free cash flow	(169)	(713)	(7,764)	(10,288)
Share buyback			(6,026)	
Payment of HIV-2 licence fee			(1,112)	
30 year Convertible Note interest payment			(2,300)	
30 year Convertible Note proceeds, net of fees		(156)		110,574
Dividend payment		(5,099)		(5,099)
Cash and cash equivalents at end of period	**84,751**	**104,289**	**84,751**	**104,289**

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: October 25, 2016.