TRINITY BIOTECH PLC
Form 6-K
October 23, 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 October, 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 October 22, 2015

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Lytham Partners LLC
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Trinity Biotech announces Quarter 3 Financial Results

DUBLIN, Ireland (October 22, 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 the quarter ended September 30, 2015.

Quarter 3 Results

Total revenues for Q3, 2015 were $25.8m which compares to $27.2m in Q3, 2014, a decrease of 5.2%. 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 on a like-for-like basis would have been $27.6m this quarter, thus representing an increase of almost 2% versus the equivalent quarter in 2014.

Point-of-Care revenues for Q3, 2015 increased slightly when compared to Q3, 2014. This increase was attributable to increased rapid syphilis sales offset by slightly lower HIV revenues.

Clinical Laboratory revenues increased to $22.1m, which represents an increase of over 2% compared to Q3, 2014. This increase was primarily attributable to increased Premier reagent and Immco revenues partly offset by lower Premier instrument and Lyme revenues.

Revenues for Q3, 2015 were as follows:

	2014 Quarter 3 US$ 000	**2015 Quarter 3 US$ 000**	**2015 Quarter 3 FX adjusted* US$ 000**	**Increase/ (decrease) %**
Point-of-Care	5,463	5,418	5,472	*0.2%*
Clinical Laboratory	21,698	20,343	22,148	*2.1%*
Total	***27,161***	***25,761***	***27,620***	***1.7%***

** Q3, 2015 revenues have been recalculated on a constant currency basis using the exchange rates prevailing in Q3, 2014*

Gross profit for Q3, 2015 amounted to $12.0m representing a gross margin of 46.5%, which is lower than the 47.9% achieved in Q3, 2014, though similar to that reported in Q2, 2014. This decrease is due to the impact of a lower level of higher margin Lyme revenues and the impact of foreign currency movements.

Research and Development expenses have increased to $1.3m from $1.1m when compared to the equivalent quarter last year. Meanwhile, Selling, General and Administrative (SG&A) expenses have increased from $7.0m to $7.5m over the same period. This increase is attributable to higher sales and marketing costs, largely due to expenditure on Meritas.

Operating profit for the quarter has decreased from $4.6m to $3.0m, thus reflecting the lower gross margin and higher indirect costs incurred this quarter.

Financial income for the quarter was $0.2m, an increase of $0.2m versus Q3, 2014 due to the higher level of funds on deposit following the issuance of the 30 Year Exchangeable Loan Notes (the Loan Notes) in Q2, 2015. Meanwhile, financial expenses increased to $1.1m mainly relating to the cash element of interest associated with these notes. The non-cash elements of the Loan Notes represented income of $10.5m which is attributable to revaluation gains on the derivatives embedded in the Loan Notes of $10.7m, partly offset by non-cash interest charges of $0.2m.

The following table summarises the impact of the Exchangeable Loan Notes on the Income Statement for Q3, 2015.

Exchangeable Loan Notes Income Statement impact	**Q3 2015 US$ 000**
Cash element	
Cash based interest charge*	(1,064)
Non-cash element	
Non-cash interest charge	(208)
Revaluation gains on embedded derivatives	10,720
Total non-cash items	*10,512*
Net financing income relating to the Exchangeable Loan notes	**9,448**

* *this is included in financial expenses in the Income Statement the remaining element ($21,000) arises on items not related to the exchangeable note.*

Profit before tax for the period was $12.6m though this was largely impacted by non-cash gains related to the Loan Notes. Excluding the non-cash elements of the Loan Notes, the profit before tax for the quarter was $2.1m.

The tax charge for Q3, 2015 was $0.3m, largely in line with the equivalent quarter in 2014.

Profit after tax for the period was $12.3m. However, excluding the non-cash elements of the Loan Notes, this would have been $1.8m, which equates to an adjusted EPS of 7.5 cents. Diluted EPS for the quarter amounted to 9.7 cents.

Cash generated from operations during the quarter was $3.7m, though this was offset by capital expenditure of $4.3m and interest and tax payments of $0.1m, resulting in a net cash outflow for the quarter of $0.7m. In addition, the company made dividend payments amounting to $5.1m with the result that the cash balance at the end of the quarter was $104.3m.

Earnings before interest, tax, depreciation, amortisation and share option expense for the quarter was $4.7m.

Other Recent Developments

Cardiac Update

The following is an update on the three main components of the Meritas Troponin-I Clinical Program:

- The most substantial component of this clinical program is the *Acute Coronary Syndrome (ACS) Study* for the evaluation of subjects presenting to the Emergency Departments with symptoms suggestive of ACS. As reported on the Q2 earnings call, enrolment for this study was completed in late July with the next step being the adjudication of each result by a panel of Emergency and Cardiology physicians. Thus far, this adjudication process, which conforms to the Third Universal Definition of Myocardial Infarction guidance document, has been more involved and time consuming than initially expected. Whilst an adjudication of clear positives or negatives can be performed in a relatively short time frame, some more complex or borderline cases are taking significantly longer in some cases as long as 2 weeks. The adjudication process is now expected to conclude by the end of November.

Based on our review of the data which has been adjudicated so far, we are pleased to report that the data is significantly better than observed in our own CE Marking trial and is closer to the superior results contained in the independent study carried out at Hennepin County Emergency Department by Dr. Fred Apple.

- Enrolment for the *URL (99th Percentile Upper Reference Limit) Study*, was completed in July and since then the data collected has been used to determined the URL or normal level of Troponin for inclusion in the FDA submission. We were very pleased to observe that the results of this study at three US trial sites show excellent correlation with the URL determinations from our European CE-marking clinical studies.

- The Precision Study is currently in the process of being completed at 3 trial sites and will be completed in the coming weeks.

From a timing perspective, the completion of the adjudication analysis of the ACS Study will be the final component to be completed and based on the timelines outlined above, we expect to submit to the FDA during December 2015.

Dividend

During Q3, following approval at the company s AGM in June 2015, an annual dividend payment of 22 US cents per ADR was made, which resulted in a total payment of $5.1m.

Comments

Commenting on the results, Kevin Tansley, Chief Financial Officer, said The profit this quarter was $12.3m. However, this was impacted by significant non-cash gains related to the company s Loan Notes. Consequently, a better way of assessing the performance this quarter is to look at operating profit, which decreased from $4.6m to $3m compared to the equivalent quarter last year. Our gross margins continue to remain under pressure due to lower Lyme revenues and currency factors. Meanwhile, indirect costs have increased due increased sales and marketing costs including continued investment in Meritas. Also, for the first time, overall profitability has been adversely impacted by exchange rate movements. Prior to this quarter, the impact of exchange rate movements had been neutral on the income statement as each of the currencies in which the company operates tended to move in tandem with each other versus the US dollar. However, in Q3 this was no longer the case with

the significant weakening of the Brazilian Real and to a lesser extent the Canadian Dollar having an adverse impact on overall profitability .

Ronan O Caoimh, CEO of Trinity said Completion of our Meritas Troponin trial constitutes an extremely important milestone for the company. We are confident that cardiologist adjudication will be completed within the next four weeks and that will enable FDA submission by the middle of December. Although the adjudication process is not yet completed, based on the results to date, we are extremely pleased with the performance of the product and in particular with its high sensitivity and specificity levels .

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, 2015 (unaudited)**	**Three Months Ended September 30, 2014 (unaudited)**	**Nine Months Ended September 30, 2015 (unaudited)**	**Nine Months Ended September 30, 2014 (unaudited)**
Revenues	**25,761**	**27,161**	**75,258**	**78,191**
Cost of sales	(13,776)	(14,150)	(39,780)	(40,510)
Gross profit	**11,985**	**13,011**	**35,478**	**37,681**
Gross profit *%*	*46.5%*	*47.9%*	*47.1%*	*48.2%*
Other operating income	73	91	222	339
Research & development expenses	(1,293)	(1,138)	(3,560)	(3,329)
Selling, general and administrative expenses	(7,467)	(6,995)	(20,467)	(19,726)
Indirect share based payments	(327)	(326)	(1,357)	(1,223)
Operating profit	**2,971**	**4,643**	**10,316**	**13,742**
Financial income	204	9	299	93
Financial expenses	(1,085)	(15)	(2,279)	(79)
Non-cash financial income	10,512		11,490	
Net financing income / (expense)	9,631	(6)	9,510	14
Profit before tax	**12,602**	**4,637**	**19,826**	**13,756**
Income tax expense	(339)	(276)	(858)	(667)

Profit for the period	**12,263**	**4,361**	**18,968**	**13,089**
Earnings per ADR (US cents)	52.9	19.0	82.0	57.7
Earnings per ADR excluding non-cash financial income (US cents)	7.5	19.0	32.3	57.7
Diluted earnings per ADR (US cents)	9.7	18.4	35.7	55.2
Weighted average no. of ADRs used in computing basic earnings per ADR	23,202,228	22,907,333	23,128,287	22,693,552
Weighted average no. of ADRs used in computing diluted earnings per ADR	28,766,691	23,674,859	27,059,058	23,719,930

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, 2015 US$ 000 (unaudited)	June 30, 2015 US$ 000 (unaudited)	March 31, 2015 US$ 000 (unaudited)	Dec 31, 2014 US$ 000 (audited)
ASSETS				
Non-current assets				
Property, plant and equipment	19,198	19,212	17,760	17,877
Goodwill and intangible assets	156,326	152,338	147,568	145,024
Deferred tax assets	10,370	10,117	9,528	9,798
Other assets	1,040	1,091	1,249	1,194
Total non-current assets	186,934	182,758	176,105	173,893
Current assets				
Inventories	36,882	38,193	37,064	33,516
Trade and other receivables	27,153	28,344	27,640	25,976
Income tax receivable	119	212	221	351
Cash and cash equivalents	104,289	110,257	5,745	9,102
Total current assets	168,443	177,006	70,670	68,945
TOTAL ASSETS	355,377	359,764	246,775	242,838
EQUITY AND LIABILITIES				
Equity attributable to the equity holders of the parent				
Share capital	1,216	1,216	1,215	1,204
Share premium	14,560	14,533	14,393	12,422
Accumulated surplus	198,882	191,368	188,094	183,375
Other reserves	(3,661)	(2,056)	(2,463)	(29)
Total equity	210,997	205,061	201,239	196,972
Current liabilities				
Income tax payable	951	497	467	785
Trade and other payables	18,694	19,756	20,116	21,197
Provisions	75	75	75	75

Total current liabilities	19,720	20,328	20,658	22,057
Non-current liabilities				
Exchangeable senior note payable	99,069	109,124		
Other payables	3,569	3,180	3,205	2,370
Deferred tax liabilities	22,022	22,071	21,673	21,439
Total non-current liabilities	124,660	134,375	24,878	23,809
TOTAL LIABILITIES	144,380	154,703	45,536	45,866
TOTAL EQUITY AND LIABILITIES	355,377	359,764	246,775	242,838

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Trinity Biotech plc

Consolidated Statement of Cash Flows

(US$000 s)	**Three Months Ended September 30, 2015 (unaudited)**	**Three Months Ended September 30, 2014 (unaudited)**	**Nine Months Ended September 30, 2015 (unaudited)**	**Nine Months Ended September 30, 2014 (unaudited)**
Cash and cash equivalents at beginning of period	**110,257**	**15,153**	**9,102**	**22,317**
Operating cash flows before changes in working capital	3,851	6,068	14,279	16,979
Changes in working capital	(166)	(538)	(8,504)	(10,108)
Cash generated from operations	3,685	5,530	5,775	6,871
Net Interest and Income taxes received/(paid)	(108)	(324)	(440)	290
Capital Expenditure & Financing (net)	(4,290)	(6,380)	(15,623)	(15,499)
Free cash flow	(713)	(1,174)	(10,288)	(8,338)
30 year Convertible Note proceeds, net of fees	(156)		110,574	
Dividend payment	(5,099)	(5,030)	(5,099)	(5,030)
Cash and cash equivalents at end of period	**104,289**	**8,949**	**104,289**	**8,949**

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 22, 2015.