

TRINITY BIOTECH PLC
Form 6-K
July 30, 2015

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

F O R M 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, 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 ☒ 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 July 28, 2015

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Trinity Biotech Announces Quarter 2 Financial Results

Enrolment for the Meritas Troponin ACS study now completed

DUBLIN, Ireland (July 28, 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 June 30, 2015.

Quarter 2 Results

Total revenues for Q2, 2015 were \$24.3m compared to \$26.0m in Q2, 2014. 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 \$25.4m this quarter, thus representing a decrease of 2%.

Point-of-Care revenues for Q2, 2015 were \$3.4m, which represents a decrease of \$1.2m on a constant currency basis. This decrease was due to lower sales of HIV products to Africa in the quarter. This reflects the irregular ordering patterns which characterize this market rather than any underlying adverse change in the nature of the business.

Clinical Laboratory revenues for the quarter were \$20.9m. However, on a constant currency basis revenues would have been \$21.9m compared to \$21.4m in Q2, 2014, an increase of 3%. This increase was due to the continued increase in Premier and Immco revenues, although this was partially offset by lower Lyme sales due to weather related factors and a decrease in Fitzgerald revenues.

Revenues for Q2, 2015 by key product area were as follows:

	2014 Quarter 2 US\$ '000	2015 Quarter 2 US\$ '000	2015 Quarter 2 FX adjusted* US\$ '000	Increase/ (decrease) %
Point-of-Care	4,615	3,371	3,447	(25%)
Clinical Laboratory	21,390	20,886	21,931	3%
Total	26,005	24,257	25,378	(2%)

* quarter 2, 2015 revenues have been recalculated on a constant currency basis using the exchange rates prevailing in Q2, 2014

Gross profit for Q2, 2015 amounted to \$11.4m, representing a gross margin of 47.0% which compares to the 48.1% achieved in Q2, 2014. This decrease is due to lower HIV and Lyme sales, both of which have higher than average

gross margins, in addition to the impact of foreign exchange movements.

Research and Development expenses have increased from \$1.2m to \$1.3m when compared to the equivalent quarter last year. Meanwhile, Selling, General and Administrative (SG&A) expenses have increased over the same period from \$6.4m to \$6.7m. This increase is due to increased pre-launch sales and marketing costs relating to Meritas, partially offset by the favourable impact of the aforementioned exchange rate movements.

The net financing expense for the quarter was \$98,000 versus \$2,000 in the equivalent quarter in 2014. However, within this quarter's expense were significant income and expense items associated with the company's 30 year Exchangeable Notes which were issued during the quarter. See below for more information on these items – a significant proportion of which are non-cash in nature.

The tax charge for Q2, 2015 was \$0.2m which equates to an effective tax rate of approximately 7% and is broadly in line with the effective rate of 6% in Q2, 2014.

Profit before tax for the quarter was \$2.9m compared to \$4.6m in Q2, 2014. Meanwhile, profit after tax for the quarter was \$2.7m versus \$4.3m for the comparative quarter. EPS for the quarter was 11.6 cents which compares to 19.0 cents for the equivalent period last year. Excluding the non-cash items arising from the accounting for the Exchangeable Notes, the EPS for the quarter would have been 7.4 cents. The fully diluted EPS for the quarter was 9.9 cents.

Earnings before interest, tax, depreciation, amortisation and share option expense for the quarter was \$5.0m. This compares to \$6.0m for Q2, 2014.

Accounting for Exchangeable Loan Notes

During Q2, 2015, Trinity Biotech issued US\$115 million of Exchangeable Loan Notes which will mature on April 1, 2045, subject to earlier repurchase, redemption or exchange. The notes are senior unsecured obligations and accrue interest at an annual rate of 4%, payable semi-annually in arrears on April 1 and October 1 of each year, beginning on October 1, 2015.

From a valuation perspective, accounting standards require the Loan Notes to be split into two parts. The first part is the derivatives embedded in the note (i.e. various put options and call options). These derivatives are initially recognised at their fair value, and at each subsequent quarterly reporting date will be revalued with any changes in value being recognised in the Income Statement within Non-Cash Financial Income/Expenses. The second part is the underlying debt liability, excluding any derivatives. The value of this part is calculated as being the total note proceeds less the fair value of the derivatives, less the directly related transaction costs.

The total interest cost relating to the notes is made up of the cash interest plus a non-cash interest element which will accrete the fair value of underlying debt liability back to its nominal value (\$115 million) over the term of the debt using an effective interest rate methodology. The cash interest of 4% is shown in the Income Statement within Financial Expenses. The non-cash interest is shown in the Income Statement within Non-Cash Financial Income.

The sum total of the non-cash interest and the change in value of the derivative instruments in the Quarter is a gain of \$978,000.

The financial expenses/(income) for the Exchangeable Loan Notes for Q2, 2015 are summarised in the table below:

Exchangeable Loan Notes	Q2 2015 US\$ '000
Financial expenses - cash element*	1,134
Non-cash financial expenses/(income)	(978)
Net financing expenses/(income) relating to the Exchangeable Loan notes	156

* the remaining element of financial expenses (\$35,000) arises on items not related to the exchangeable note.

Cardiac Update

During Q2, significant progress has been made in relation to the preparation of Meritas Troponin I for submission to the FDA. Firstly and very importantly, we are happy to report that enrolment to the Troponin ACS (Acute Coronary Syndrome) clinical study, which had been carried out at 12 clinical trial sites across the USA, is now complete. The company has reached its goal of recruiting close to 1,500 patients presenting in the Emergency Room with symptoms suggestive of ACS thus generating 150 actual ACS patients. The complete ACS patient cohort is currently being put through the cardiologist adjudication process.

Moreover, enrolment into the URL Study (Upper Reference Limit or 99th Percentile) is also complete, with the company having recruited sufficient normal patient samples, across three US sites, to be able to calculate a statistically significant URL value (99th percentile value) for its Troponin I product in a US normal population.

With the two main components of the Troponin Trial now complete, and although results of the adjudication process remain unknown to us, we are very encouraged by the trial data that we have seen.

Still remaining to be completed is a precision study which will be run at three US sites. This study consists of running high, medium and low Troponin controls and patient samples for 20 consecutive days. This study will run concurrently with the ACS adjudication process and is expected to end slightly ahead of adjudication.

Finally, preparation of our FDA submission document is at an advanced stage. It essentially awaits the final outcome from the trial data sets to be ready for submission. The company now estimates that the adjudication process will be completed by the end of August with submission of the application to the FDA expected by end of September or early October.

Significant progress has also been made on the second test to be launched on the Meritas platform, Meritas BNP. Following a clarification call with the FDA on July 13th, and in accordance with the recommendation that utilisation of banked clinical samples should be avoided, it has been decided to increase the number of US trial sites to 12. This will have the effect of pushing FDA submission out by 3 to 4 months. However, because the BNP trial is considerably simpler than the Troponin trial, approval is still expected to be received ahead of Troponin.

Dividend

Shareholder approval for payment of a dividend of 22 US cents per ADR was granted at the company's AGM, which was held on 5 June, 2015. Payment of the dividend was made in early July 2015.

Comments

Commenting on the results, Kevin Tansley, Chief Financial Officer, said Trinity Biotech earned profits of \$2.7m this quarter which is a reduction from \$4.3m in the comparative quarter last year. A major contributory factor was a drop of \$1.5m in HIV revenues in Africa. However, this was due to the inherent variability and unpredictability of such sales rather than any underlying change in this market or Trinity's position within it. Profits were also impacted by lower sales of higher margin Lyme products and higher sales and marketing expenses largely driven by costs incurred in relation to our Troponin product.

Ronan O Caoimh, CEO, stated Completion of the ACS trial for our Meritas Troponin test represents an extremely important milestone for the Company. In relation to the results of the trial, although the adjudication process is not completed, we can see the actual hospital diagnosis on the patient samples and although there is no guarantee that the hospital result will agree with the adjudicated result in every case, we are very encouraged by the trial results. We will now complete the last remaining elements of the trial and will make our submission to the FDA in late September or early October.

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	Three Months	Six Months	Six Months
	Ended	Ended	Ended	Ended
	June 30,	June 30,	June 30,	June 30,
	2015	2014	2015	2014
<i>(US\$000 s except share data)</i>	<i>(unaudited)</i>	<i>(unaudited)</i>	<i>(unaudited)</i>	<i>(unaudited)</i>
Revenues	24,257	26,005	49,267	51,030
Cost of sales	(12,864)	(13,496)	(25,869)	(26,360)
Gross profit	11,393	12,509	23,398	24,670
Gross profit %	47.0%	48.1%	47.5%	48.3%
Other operating income	72	98	150	248
Research & development expenses	(1,269)	(1,155)	(2,267)	(2,192)
Selling, general and administrative expenses	(6,713)	(6,417)	(12,905)	(12,730)
Indirect share based payments	(473)	(442)	(1,031)	(897)
Operating profit	3,010	4,593	7,345	9,099
Financial income	93	42	94	84
Financial expenses	(1,169)	(44)	(1,193)	(64)
Non-cash financial income	978		978	
Net financing income / (expense)	(98)	(2)	(121)	20
Profit before tax	2,912	4,591	7,224	9,119
Income tax expense	(218)	(276)	(522)	(391)
Profit for the period	2,694	4,315	6,702	8,728
Earnings per ADR (US cents)	11.6	19.0	29.0	38.6
Earnings per ADR excluding non-cash financial income (US cents)	7.4	19.0	24.8	38.6
Diluted earnings per ADR (US cents)	9.9	18.2	26.1	36.8
Weighted average no. of ADRs used in computing basic earnings per ADR	23,195,016	22,703,261	23,090,704	22,584,889
Weighted average no. of ADRs used in computing diluted earnings per ADR	28,812,187	23,686,336	26,285,071	23,720,056

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, 2015 US\$ 000 (unaudited)	March 31, 2015 US\$ 000 (unaudited)	Dec 31, 2014 US\$ 000 (audited)
ASSETS			
Non-current assets			
Property, plant and equipment	19,212	17,760	17,877
Goodwill and intangible assets	152,338	147,568	145,024
Deferred tax assets	10,117	9,528	9,798
Other assets	1,091	1,249	1,194
Total non-current assets	182,758	176,105	173,893
Current assets			
Inventories	38,193	37,064	33,516
Trade and other receivables	28,344	27,640	25,976
Income tax receivable	212	221	351
Cash and cash equivalents	110,257	5,745	9,102
Total current assets	177,006	70,670	68,945
TOTAL ASSETS	359,764	246,775	242,838
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the parent			
Share capital	1,216	1,215	1,204
Share premium	14,533	14,393	12,422
Accumulated surplus	191,368	188,094	183,375
Other reserves	(2,056)	(2,463)	(29)
Total equity	205,061	201,239	196,972
Current liabilities			
Income tax payable	497	467	785
Trade and other payables	19,756	20,116	21,197
Provisions	75	75	75
Total current liabilities	20,328	20,658	22,057
Non-current liabilities			
Exchangeable senior note payable	109,124		

Other payables	3,180	3,205	2,370
Deferred tax liabilities	22,071	21,673	21,439
Total non-current liabilities	134,375	24,878	23,809
TOTAL LIABILITIES	154,703	45,536	45,866
TOTAL EQUITY AND LIABILITIES	359,764	246,775	242,838

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

	Three Months	Three Months	Six Months	Six Months
	Ended	Ended	Ended	Ended
	June 30,	June 30,	June 30,	June 30,
	2015	2014	2015	2014
<i>(US\$000 s)</i>	<i>(unaudited)</i>	<i>(unaudited)</i>	<i>(unaudited)</i>	<i>(unaudited)</i>
Cash and cash equivalents at beginning of period	5,744	17,008	9,102	22,317
Operating cash flows before changes in working capital	4,130	5,919	10,428	10,911
Changes in working capital	(2,906)	(4,309)	(8,337)	(9,571)
Cash generated from operations	1,224	1,610	2,091	1,340
Net Interest and Income taxes (paid)/received	(223)	611	(332)	614
Capital Expenditure & Financing (net)	(7,218)	(4,076)	(11,334)	(9,118)
Free cash flow	(6,217)	(1,855)	(9,575)	(7,164)
30 year Convertible Note proceeds, net of fees	110,730		110,730	
Cash and cash equivalents at end of period	110,257	15,153	110,257	15,153

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 28, 2015.