TRINITY BIOTECH PLC
Form 6-K
April 19, 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 April, 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 April 19, 2016

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**Trinity Biotech Announces Results for Q1, 2016**

**DUBLIN, Ireland (April 19, 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 March 31, 2016.

**Quarter 1 Results**

Total revenues for Q1, 2016 were $23.5m which compares to $25.2m in Q1, 2015, a decrease of 7%. 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 $24.3m this quarter, thus representing a decrease of 4% versus the equivalent quarter in 2015.

| | **2015 Quarter 1 US$ 000** | **2016 Quarter 1 US$ 000** | **2016 Quarter 1 FX adjusted* US$ 000** | **Increase/ (decrease) %** |
|---|---|---|---|---|
| Point-of-Care | 4,585 | 3,268 | 3,287 | *(28%)* |
| Clinical Laboratory | 20,655 | 20,248 | 21,037 | *2%* |
| ***Total*** | ***25,240*** | ***23,516*** | ***24,324*** | ***(4%)*** |

* *Q1, 2016 revenues have been recalculated on a constant currency basis using the exchange rates prevailing in Q1, 2015*

Point-of-Care revenues for Q1, 2016 fell by $1.3m compared to Q1, 2015. This was attributable to lower than expected HIV sales in Africa. Such fluctuations are a feature of the African HIV market which exhibits irregular ordering patterns from customers. Meanwhile, Clinical Laboratory revenues increased from $20.7m to $21.0m, an increase of 2% compared to Q1, 2015 mainly due to higher Premier and Immco revenues.

Gross margins for the quarter were 43.1%. This is lower than the gross margin reported in Q1, 2015 of 47.9% though was similar to the 43.2% reported in Q4, 2015. Production levels were lower in response to this quarter s lower revenues thus resulting in an underabsorption of fixed labour and overhead costs and hence resulting in lower gross margins. It was also impacted by lower HIV sales, which tend to have higher than average margins.

Research and Development expenses increased from $1m to $1.1m. Meanwhile Selling, General and Administrative (SG&A) expenses increased from $6.3m to $7.0m, mainly due to non-cash foreign currency retranslation charges.

Operating profit for the quarter decreased from $4.3m to $1.8m largely due to the lower revenues and gross margin this quarter.

Financing expenses for the quarter amounted to $3m. Of this, $0.2m consisted of deposit interest income and $1.2m of interest payable on the Company s exchangeable notes. A further non-cash charge of $2m was recognised in the quarter mainly due an increase in the fair value of the embedded derivatives associated with these exchangeable notes.

The Company recorded a loss of $1.3m for the quarter which equated to a loss per share of 5.8 cents. However, excluding non-cash items the profit for the quarter was $0.7m or an EPS of 2.9 cents. Fully diluted EPS for the quarter was 6.4 cents.

EBITDA before share option expense for the quarter was $3.4m.

***Cardiac Update***

Trinity submitted a 510(k) application for its high sensitivity cardiac Troponin-I assay and Meritas Point-of-Care Analyzer to the FDA at the end of 2015. The application is being reviewed according to the FDA s published review process, and is currently in the substantive review phase. We are happy that the review process and our interactions with the FDA are proceeding well and in accordance with our expectations. As part of this review process, the Company has received a detailed list of questions and comments from the FDA. We are now working through this list and are confident that comprehensive responses can be provided to satisfactorily address all of the FDA s questions.

The US clinical validation studies in support of a 510(k) submission to the FDA for a second cardiac marker assay, B-type Natriuretic Protein (BNP), are progressing well. There are 10 clinical sites, geographically dispersed across the US, that are actively enrolling. Enrolment is currently 70% complete and is on track to be fully completed by the end of Q2, 2016. Consequently, 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 132,000 ADRs at an average price of $11.41. The total value of the repurchases was $1.5m, of which $1.3m was settled during the quarter.

**Comments**

Commenting on the results, Kevin Tansley, Chief Financial Officer, said Results this quarter were adversely impacted by lower HIV sales in Africa. However these lower sales were driven by the variable sales patterns that characterise this market, rather than by any deterioration in the underlying business. The decrease of the relatively higher margin HIV sales, resulted in both lower gross margins and operating profit being reported this quarter. Notwithstanding this, the Company achieved operating profits of over $1.8m. Meanwhile, excluding non-cash items relating to the Company s exchangeable notes, profit after tax for the quarter amounted to $0.7m.

Ronan O Caoimh, CEO of Trinity said At the end of 2015 we submitted our Meritas Troponin product to the FDA. We recently received the FDA s formal review document relating to this submission and we are pleased to state that we are confident of addressing all of their queries by the end of July. We are also making excellent progress with our BNP trials and we remain on target to submit this product to the FDA during quarter 3, this year.

We recently announced the commencement of a share buyback program as we felt that this represented the best deployment of the Company s capital, particularly given its current share price. During the quarter a total of 132,000 shares with a value of $1.5m were repurchased. We intend to continue repurchasing in the months ahead, though the exact number of shares that will be repurchased will depend on market conditions, whilst being subject to applicable securities laws and regulations.

*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 Mar 31, 2016 (unaudited)** | **Three Months Ended Dec 31, 2015 (unaudited)** | **Three Months Ended Mar 31, 2015 (unaudited)** |
|---|---|---|---|
| **Revenues** | **23,516** | **24,937** | **25,240** |
| Cost of sales | (13,385) | (14,170) | (13,140) |
| **Gross profit** | **10,131** | **10,767** | **12,100** |
| Gross profit *%* | *43.1%* | *43.2%* | *47.9%* |
| Other operating income | 69 | 65 | 78 |
| Research & development expenses | (1,147) | (1,508) | (998) |
| Selling, general and administrative expenses | (6,961) | (6,009) | (6,287) |
| Indirect share based payments | (267) | (184) | (558) |
| **Operating profit** | **1,825** | **3,131** | **4,335** |
| Financial income | 220 | 132 | 1 |
| Financial expenses | (1,181) | (1,189) | (24) |
| Non-cash financial (expense) / income | (2,029) | 975 | |
| **Net financing (expense) / income** | (2,990) | (82) | (23) |
| **Profit / (loss) before tax** | **(1,165)** | **3,049** | **4,312** |
| Income tax expense | (182) | (223) | (304) |
| **Profit / (loss) for the period** | **(1,347)** | **2,826** | **4,008** |
| Earnings per ADR (US cents) | (5.8) | 12.1 | 17.0 |
| Earnings per ADR excluding non-cash financial income (US cents) | 2.9 | 8.0 | 17.0 |
| Diluted earnings per ADR (US cents) | 6.4* | 10.5 | 17.4 |
| Weighted average no. Of ADRs used in computing basic earnings per ADR | 23,287,867 | 23,259,669 | 22,985,234 |
| Weighted average no. Of ADRs used in computing diluted earnings per ADR | 28,656,394 | 28,690,599 | 23,604,244 |

* 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 a loss of 5.8 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**

| | Mar 31, 2016 US$ 000 (unaudited) | Dec 31, 2015 US$ 000 (unaudited) |
|---|---|---|
| **ASSETS** | | |
| **Non-current assets** | | |
| Property, plant and equipment | 21,460 | 20,659 |
| Goodwill and intangible assets | 165,157 | 161,324 |
| Deferred tax assets | 13,096 | 12,792 |
| Other assets | 860 | 954 |
| **Total non-current assets** | 200,573 | 195,729 |
| **Current assets** | | |
| Inventories | 35,709 | 35,125 |
| Trade and other receivables | 26,260 | 25,602 |
| Income tax receivable | 664 | 550 |
| Cash and cash equivalents | 96,829 | 101,953 |
| **Total current assets** | 159,462 | 163,230 |
| **TOTAL ASSETS** | 360,035 | 358,959 |
| **EQUITY AND LIABILITIES** | | |
| **Equity attributable to the equity holders of the parent** | | |
| Share capital | 1,220 | 1,220 |
| Share premium | 15,521 | 15,526 |
| Accumulated surplus | 199,453 | 201,951 |
| Other reserves | (3,723) | (4,809) |
| **Total equity** | 212,471 | 213,888 |
| **Current liabilities** | | |
| Income tax payable | 1,026 | 1,163 |
| Trade and other payables | 19,195 | 18,874 |
| Provisions | 75 | 75 |
| **Total current liabilities** | 20,296 | 20,112 |
| **Non-current liabilities** | | |
| Exchangeable senior note payable | 100,073 | 98,044 |

| | | |
|---|---|---|
| Other payables | 2,057 | 2,096 |
| Deferred tax liabilities | 25,138 | 24,819 |
| **Total non-current liabilities** | 127,268 | 124,959 |
| **TOTAL LIABILITIES** | 147,564 | 145,071 |
| **TOTAL EQUITY AND LIABILITIES** | 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 March 31, 2016 (unaudited)** | **Three Months Ended March 31, 2015 (unaudited)** |
|---|---|---|
| **Cash and cash equivalents at beginning of period** | **101,953** | **9,102** |
| Operating cash flows before changes in working capital | 2,503 | 6,298 |
| Changes in working capital | (628) | (4,322) |
| Cash generated from operations | 1,875 | 1,976 |
| Net Interest and Income taxes (paid)/received | (241) | (108) |
| Capital Expenditure & Financing (net) | (5,431) | (4,113) |
| Free cash flow | (3,797) | (2,245) |
| Payment of HIV-2 licence fee | | (1,112) |
| Share buyback | (1,327) | |
| **Cash and cash equivalents at end of period** | **96,829** | **5,745** |

*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: April 19, 2016.