

TRINITY BIOTECH PLC  
Form 6-K  
March 08, 2019

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SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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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 March, 2019

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):  
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Press Release dated March 7, 2019

|  |                                    |
|--|------------------------------------|
| Contact: <b>Trinity Biotech plc</b>  | Lytham Partners LLC                |
| Kevin Tansley  | Joe Diaz, Joe Dorame & Robert Blum |
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Trinity Biotech announces Quarter 4 and Fiscal Year 2018 Financial Results

DUBLIN, Ireland (March 7, 2019).... 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 December 31, 2018 and fiscal year 2018.

Fiscal Year 2018 Results

Total revenues for fiscal year 2018 were \$97.0m versus \$99.1m in 2017, a decrease of 2% year on year and were broken down as follows:

|                     | Full<br>Year<br>2017<br>US\$'000 | Full<br>Year<br>2018<br>US\$'000 | Full<br>Year<br>2018<br>vs<br>2017<br>% |
|---------------------|----------------------------------|----------------------------------|---|
| Point-of-Care       | 16,774                           | 14,836                           | (11.6)%                                 |
| Clinical Laboratory | 82,366                           | 82,199                           | (0.2 )%                                 |
| Total               | 99,140                           | 97,035                           | (2.1 )%                                 |

Point-of-Care revenues decreased from \$16.8m in 2017 to \$14.8m in 2018, which represents a decrease of 11.6%. This was mainly attributable to lower HIV sales in Africa due to erratic ordering patterns and was contributed to by the impact of significant overstocking by one larger customer which occurred during 2017. Meanwhile, HIV sales in the USA continued to be lower due to constraints on federally funded public health programs.

Clinical Laboratory revenues were \$82.2m, which is broadly flat when compared with 2017. During the year, Diabetes and Autoimmunity revenues continued their upward growth trajectory. However, this growth was offset by lower Lyme revenues due to the loss of a significant contract with one of the major clinical laboratory service providers in the USA. Revenues were also adversely impacted by foreign exchange movements and this was most pronounced in Brazil where the Real was over 14% weaker year on year.

The gross margin for the year was 42.7% compared to 42.3% in 2017. This increase was mainly attributable to cost savings implemented during the year, the benefit of which outweighed the negative impact of lower point-of-care revenues and adverse currency movements.

Research and Development expenses for the year decreased from \$5.7m to \$5.4m, a decrease of \$0.3m. Meanwhile, Selling General and Administrative (SG&A) expenses decreased from \$30m to \$28.2m, a decrease of 6%. In both cases the main driver has been the impact of cost savings, though in the case of SG&A expenses a gain recognised in Q3, 2018 on a partial buyback of the company's Exchangeable Notes was also a contributory factor.

Operating profit for the year increased from \$5.5m to \$6.7m in 2018. This increase was mainly attributable to lower indirect costs and to a lesser extent the increase in gross margin.

Profit after tax (before the impact of once-off items & non-cash financial income) increased to \$2.4m from \$2.3m in 2017. Whilst operating profit was significantly higher in 2018 it was offset by tax movements. In 2017 the Company recorded an overall tax credit of \$0.7m due to the impact of changes in U.S. tax code on the Company's deferred tax balances. Meanwhile, in 2018, we returned to the more normal position of a tax charge of \$0.6m which equates to an effective tax charge of 9.5%.

Basic EPS (excluding once-off charges & non-cash financial income) for the year was 11.4 cents versus 10.6 cents in 2017. Meanwhile, unconstrained diluted EPS was 26.0 cents compared to 25.7 cents in 2017.

Earnings before interest, tax, depreciation, amortisation and share option expense for the year was \$12.1m.

The above measures exclude the impact of an impairment charge of \$25.2m net of tax, more details of which are provided below.

#### Quarter 4 Results

Total revenues for Q4, 2018 were \$24.5m which compares to \$24.6m in Q4, 2017 and were broken down as follows:

|                     | 2017<br>Quarter<br>4<br>US\$'000 | 2018<br>Quarter<br>4<br>US\$'000 | Increase/<br>(decrease)<br>% |    |
|---------------------|----------------------------------|----------------------------------|------------------------------|----|
| Point-of-Care       | 3,817                            | 4,037                            | 5.8                          | %  |
| Clinical Laboratory | 20,735                           | 20,487                           | (1.2)                        | )% |
| Total               | 24,552                           | 24,524                           | (0.1)                        | )% |

Point-of-Care revenues increased by 5.8% to over \$4m in Q4, 2018. This was driven by higher HIV sales in Africa. Whilst the impact of the significant fluctuations which characterize this product line were a negative for the year as a whole, in Q4, 2018 it represented a positive factor. Part of this growth was offset by slightly lower HIV sales in the USA.

Clinical Laboratory revenues decreased from \$20.7m to \$20.5m, which represents a decrease of 1.2% compared to Q4, 2017. This decrease was due to the impact of higher Diabetes and Autoimmunity revenues being offset by lower Lyme sales and adverse currency movements.

Gross profit for Q4, 2018 amounted to \$10.2m representing a gross margin of 41.7% which represents an improvement compared to the 41.5% reported in the equivalent quarter last year. As was the case for the year as a whole, the gain was achieved through the cost savings program implemented during 2018 and this served to offset the impact of higher instrument sales and adverse currency movements this quarter.

Research and Development expenses of \$1.4m were lower than the equivalent quarter last year (\$1.5m) whilst Selling, General and Administrative (SG&A) were also lower for the quarter at \$6.8m which represents a decrease of \$0.9m

compared to Q4, 2017. Again, these reductions were attributable to cost savings implemented earlier in the year.

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The combined impact of lower indirect costs and a slightly higher gross margin resulted in an increase in operating profit for the quarter from \$0.8m to \$1.9m.

The profit after tax, before once-off charges and non-cash financial income, for the quarter was \$0.8m compared to \$0.9m for the equivalent period last year. This decrease was due to a large tax credit (\$1m) due to U.S. tax code changes arising in Q4, 2017 compared to a tax charge of \$0.3m in Q4, 2018 thus offsetting the significant improvement in operating profit during Q4, 2018.

The basic EPS (excluding once-off charge and non-cash financial income) for the quarter was 3.8 cents versus 4.2 cents in Q4, 2017. Unconstrained diluted EPS for the quarter amounted to 7.0 cents, which compares to 7.7 cents in the equivalent quarter in 2017.

Cash generated from operations during the quarter was \$0.2m, interest and taxes received was \$1.4m, and these were offset by capital expenditure of \$5m and thus resulting in free cash outflows for the quarter of \$3.4m. Other major cash outflows for the quarter included interest payments of \$2m. Overall, this resulted in a cash balance at the end of the year of \$30.3m.

Earnings before interest, tax, depreciation, amortisation and share option expense for the quarter was \$3.2m.

The above measures exclude the impact of impairment charges amounting to \$25.2m net of tax, more details of which are provided below.

### Impairment

In accordance with the provisions of accounting standards, a company is required to carry out an annual impairment review in order to determine the appropriate carrying value of its net assets. This year's review has resulted in a non-cash impairment charge of \$25.2m net of tax being recognised. A number of factors impacted this calculation including:

- the Company's market capitalisation at the end of the year, which was lower when compared to the end of 2017;
- the inclusion of the latest cash flow projections and net asset values for each of the company's individual cash generating units; and
- increased volatility in the Company's share price and higher market interest rates which resulted in a higher cost of capital being attributable to the Company's expected future cash flows.

### Comments

Commenting on the results Kevin Tansley, Chief Financial Officer stated "Today's results for 2018 show a significant increase in operating profit which grew by 22% to \$6.7m. This was achieved primarily due to substantial cost savings, which were implemented during the year, which resulted in higher gross margins, despite the headwinds of a less favourable sales mix and adverse currency movements. These cost savings also resulted in significantly lower indirect costs for the year. The improvement in operating profit would have translated into a commensurate increase in profit after tax and EPS but for a once-off tax credit, which was recognised in late 2017 at the time when significant changes in the U.S. tax code were enacted.

Our results for Q4, 2018 also show improved operating profitability which more than doubled to \$1.9m for the quarter. This quarter's results also include an impairment charge of \$25.2m net of tax which is non-cash in nature and arises due to the accounting requirements governing annual impairment reviews."

Commenting, Ronan O'Caomh, Chief Executive Officer stated "Our total revenues for 2018 were \$97m and this compares to \$99.1m in 2017, a reduction of 2%. The entire reduction equated to the reduction we saw in our in our

point-of-care revenues which were 11.6% down compared to last year. This mainly arose in the African market, where sales are more erratic and variable in nature and was in a large part due to overstocking in one of the larger countries in which we operate. However, of key importance is that we retained all of our customers and testing algorithm positions, thus preserving our dominance of the HIV confirmatory market in Africa. We also have a major opportunity to take a significant share of the much larger screening market with our forthcoming launch of our Trin-Screen product, which has been specifically designed to address the screening market.

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Meanwhile, our Clinical Laboratory revenues were broadly flat for the year. I am pleased to say that we are continuing to build on our track record of growth in our Diabetes and Autoimmunity product lines both of which grew solidly during the year. Future growth can be expected as we rollout our Premier Resolution and our Diabetes point-of-care device, Tri-Stat. Similarly, future growth in Autoimmunity revenues will be driven by higher laboratory testing volumes combined with a greater emphasis of product sales culminating in the launch of a new automated reader in 2020.

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](http://www.trinitybiotech.com).

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Trinity Biotech plc  
Consolidated Income Statements

|   | Three<br>Months<br>Ended<br>Dec 31,<br>2018<br>(unaudited) | Three<br>Months<br>Ended<br>Dec 31,<br>2017<br>(unaudited) | Year<br>Ended<br>Dec 31,<br>2018<br>(unaudited) | Year<br>Ended<br>Dec 31,<br>2017<br>(unaudited) |
|---|--|--|---|---|
| (US\$000's except share data)   |  |  |   |   |
| Revenues  | 24,524   | 24,552   | 97,035  | 99,140  |
| Cost of sales   | (14,290 )  | (14,370 )  | (55,586 )                                       | (57,251 )                                       |
| Gross profit  | 10,234   | 10,182   | 41,449  | 41,889  |
| Gross profit %  | 41.7 %   | 41.5 %   | 42.7 %  | 42.3 %  |
| Other operating income  | 26   | 27   | 102   | 101   |
| Research & development expenses                                       | (1,386 )   | (1,539 )   | (5,369 )  | (5,658 )  |
| Selling, general and administrative expenses                          | (6,752 )   | (7,611 )   | (28,164 )                                       | (29,961 )                                       |
| Indirect share based payments   | (205 )   | (249 )   | (1,335 )  | (893 )  |
| Operating profit  | 1,917  | 810  | 6,683   | 5,478   |
| Financial income  | 158  | 224  | 735   | 808   |
| Financial expenses  | (1,012 )   | (1,176 )   | (4,391 )  | (4,682 )  |
| Net financing expense   | (854 )   | (952 )   | (3,656 )  | (3,874 )  |
| Profit/(Loss) before tax, non-cash & once-off items                   | 1,063  | (142 )   | 3,027   | 1,604   |
| Income tax (expense) / credit   | (271 )   | 1,028  | (637 )  | 697   |
| Profit after tax before non-cash & once-off items                     | 792  | 886  | 2,390   | 2,301   |
| Non-cash financial income   | 431  | 489  | 700   | 1,667   |
| Impairment & once-off items (net of tax)                              | (25,180 )  | (44,238 )  | (25,180 )                                       | (44,238 )                                       |
| Loss after tax and once-off items                                     | (23,957 )  | (42,863 )  | (22,090 )                                       | (40,270 )                                       |
| Loss per ADR (US cents)   | (114.6 )   | (202.9 )   | (105.7 )  | (186.2 )  |
| Earnings per ADR (US cents)**   | 3.8  | 4.2  | 11.4  | 10.6  |
| Diluted loss per ADR (US cents)                                       | (91.8 )*   | (159.9 )*  | (71.3 )*  | (138.9 )*                                       |
| Diluted earnings per ADR (US cents)**                                 | 7.0 *  | 7.7 *  | 26.0 *  | 25.7 *  |
| Weighted average no. of ADRs used in computing basic earnings per ADR | 20,901,703   | 21,129,969   | 20,903,227                                      | 21,621,602                                      |
|   | 25,467,516   | 26,385,912   | 25,877,205                                      | 26,877,545                                      |



Weighted average no. of ADRs used in computing  
diluted earnings per ADR

\* Under IAS 33 Earnings per Share, diluted earnings per share cannot be anti-dilutive. Therefore, diluted loss per ADR in accordance with IFRS would be equal to basic earnings per ADR.

\*\* Excluding once-off charges & non-cash financial income. The once-off item in the current year does not include the results of Fiom Diagnostics.

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). Once-off charges is a non-GAAP accounting presentation.

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Trinity Biotech plc  
Consolidated Balance Sheets

|   | Dec 31,<br>2018<br>US\$ '000<br>(unaudited) | Sept 30,<br>2018<br>US\$ '000<br>(unaudited) | June 30,<br>2018<br>US\$ '000<br>(unaudited) | Dec 31,<br>2017<br>US\$ '000<br>(unaudited) |
|---|---|--|--|---|
| <b>ASSETS</b>   |   |  |  |   |
| Non-current assets                                      |   |  |  |   |
| Property, plant and equipment                           | 5,362                                       | 10,046                                       | 7,769  | 5,800                                       |
| Goodwill and intangible assets                          | 52,951                                      | 69,804                                       | 68,263                                       | 64,754                                      |
| Deferred tax assets                                     | 5,703                                       | 9,342  | 9,047  | 8,698                                       |
| Other assets  | 558   | 656  | 701  | 771   |
| Total non-current assets                                | 64,574                                      | 89,848                                       | 85,780                                       | 80,023                                      |
| Current assets  |   |  |  |   |
| Inventories   | 30,359                                      | 32,888                                       | 34,818                                       | 32,805                                      |
| Trade and other receivables                             | 24,441                                      | 23,380                                       | 23,138                                       | 20,740                                      |
| Income tax receivable                                   | 1,584                                       | 1,532  | 1,287  | 1,440                                       |
| Cash, cash equivalents and deposits                     | 30,277                                      | 35,679                                       | 49,426                                       | 57,607                                      |
| Total current assets                                    | 86,661                                      | 93,479                                       | 108,669                                      | 112,592                                     |
| <b>TOTAL ASSETS</b>                                     | <b>151,235</b>                              | <b>183,327</b>                               | <b>194,449</b>                               | <b>192,615</b>                              |
| <b>EQUITY AND LIABILITIES</b>                           |   |  |  |   |
| Equity attributable to the equity holders of the parent |   |  |  |   |
| Share capital   | 1,224                                       | 1,224  | 1,224  | 1,224                                       |
| Share premium   | 16,187                                      | 16,187                                       | 16,187                                       | 16,187                                      |
| Accumulated surplus                                     | 24,368                                      | 48,325                                       | 47,430                                       | 46,157                                      |
| Other reserves  | 2,275                                       | 2,347  | 1,853  | 1,628                                       |
| Total equity  | 44,054                                      | 68,083                                       | 66,694                                       | 65,196                                      |
| Current liabilities                                     |   |  |  |   |
| Income tax payable                                      | 210   | 135  | 252  | 310   |
| Trade and other payables                                | 17,344                                      | 20,682                                       | 20,494                                       | 20,845                                      |
| Provisions  | 50  | 50   | 50   | 75  |
| Total current liabilities                               | 17,604                                      | 20,867                                       | 20,796                                       | 21,230                                      |
| Non-current liabilities                                 |   |  |  |   |
| Exchangeable senior note payable                        | 81,620                                      | 82,051                                       | 95,179                                       | 94,825                                      |
| Other payables  | 526   | 498  | 341  | 532   |
| Deferred tax liabilities                                | 7,431                                       | 11,828                                       | 11,439                                       | 10,832                                      |
| Total non-current liabilities                           | 89,577                                      | 94,377                                       | 106,959                                      | 106,189                                     |
| <b>TOTAL LIABILITIES</b>                                | <b>107,181</b>                              | <b>115,244</b>                               | <b>127,755</b>                               | <b>127,419</b>                              |
| <b>TOTAL EQUITY AND LIABILITIES</b>                     | <b>151,235</b>                              | <b>183,327</b>                               | <b>194,449</b>                               | <b>192,615</b>                              |

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<br>Months<br>Ended<br>Dec 31,<br>2018<br>(unaudited) | Three<br>Months<br>Ended<br>Dec 31,<br>2017<br>(unaudited) | Year<br>Ended<br>Dec 31,<br>2018<br>(unaudited) | Year<br>Ended<br>Dec 31,<br>2017<br>(unaudited) |
|--|--|--|---|---|
| (US\$000's)  |  |  |   |   |
| Cash and cash equivalents at beginning of period       | 35,679   | 62,529   | 57,607  | 77,108  |
| Operating cash flows before changes in working capital | 3,168  | 3,088  | 13,075  | 12,768  |
| Changes in working capital                             | (2,939 )   | 1,727  | (7,596 )  | (535 )  |
| Cash generated from operations                         | 229  | 4,815  | 5,479   | 12,233  |
| Net Interest and Income taxes received/(paid)          | 1,406  | (445 )   | 1,456   | (121 )  |
| Capital Expenditure & Financing (net)                  | (5,039 )   | (4,696 )   | (17,286 )                                       | (15,255 )                                       |
| Free cash flow   | (3,404 )   | (326 )   | (10,351 )                                       | (3,143 )  |
| Share buyback  | -  | (1,327 )   | (434 )  | (7,799 )  |
| Once-off items   | -  | (969 )   | (12,042 )                                       | (3,959 )  |
| 30 year Exchangeable Note interest payment             | (1,998 )   | (2,300 )   | (4,503 )  | (4,600 )  |
| Cash and cash equivalents at end of period             | 30,277   | 57,607   | 30,277  | 57,607  |

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: 8 March 2019

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