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Trinity Biotech announces Quarter 4 and Fiscal Year 2019 Financial Results

DUBLIN, Ireland (March 31, 2020)…. 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, 2019 and fiscal year 2019.

Fiscal Year 2019 Results

Total revenues for fiscal year 2019 were $90.4m versus $97.0m in 2018, a decrease of 6.8% year on year and were broken down as follows:

	Full Year 2018	**Full Year 2019**	**Full Year 2019 vs 2018**
	US$'000	**US$'000**	**%**
Point-of-Care	14,836	11,393	(23.2)
Clinical Laboratory	82,199	79,042	(3.8)
Total	**97,035**	**90,435**	**(6.8)**

Point-of-Care revenues decreased from $14.8m in 2018 to $11.4m in 2019, which represents a decrease of 23.2%. This decrease was due to lower HIV sales, particularly in the USA. Meanwhile, African sales were down modestly in 2019 compared to 2018 due to the normal fluctuations that characterise this market rather than due to any loss of customers.

Clinical Laboratory revenues were $79.0m, which represents a decrease of 3.8% when compared with 2018. Diabetes and Autoimmunity revenues continued to grow in 2019. However, this growth was offset by a decline in Infectious Diseases revenues primarily due to lower Lyme sales attributable to the loss of a contract with one of the major U.S. clinical laboratory service providers and the continued migration away from Western Blot to other testing formats. Revenues were also adversely impacted by foreign exchange movements, in particular the increasing strength of the U.S. dollar versus the Brazilian Real, Euro, Sterling and Canadian dollar.

The gross margin for the year was 42.2% compared to 42.7% in 2018. This decrease was mainly due to the impact of lower revenues, particularly in the context of our relatively high fixed cost base and the

adverse currency movements mentioned above. This was partly offset by selling price increases and cost savings that were implemented during the year.

Research and Development expenses showed a slight reduction from $5.4m to $5.3m year on year. Meanwhile, Selling General and Administrative (SG&A) expenses decreased from $28.2m to $26.9m, a decrease of 4.6%. In both cases, the main driver has been the impact of planned cost savings. In the case of SG&A expenses, there was also a reduction of $0.5m due to the introduction of *IFRS 16 Leases* though this is broadly equivalent to a gain recognised on the partial buyback of the Company's Exchangeable Notes in 2018.

Operating profit for the year decreased from $6.7m to $5.3m in 2019. This decrease was mainly attributable to lower revenues and to a lesser extent the lower gross margin. These factors were in turn offset by a $2.0m reduction in indirect costs from $34.9m to $32.9m.

The net financing expense for the year increased from $3.7m to $4.5m due to the inclusion of a notional interest charges on facility leases of $0.9m due to the implementation of IFRS 16 and lower deposit interest, offset by a reduction in interest payable on our Exchangeable Notes of $0.4m following the buyback of a portion of the notes in 2018.

Profit before tax (before the impact of once-off items & non-cash financial income) for 2019 was $0.8m, a reduction of $2.2m versus 2018.

Meanwhile, there was a loss after tax (before the impact of once-off items & non-cash financial income) of $4.1m in 2019 compared with a profit of $2.4m in 2018. In addition to the lower profit before tax this was due to a higher tax charge in 2019 mainly due to the cost of settling a tax audit in one of the jurisdictions in which the Company operates. However, as you will see from the Q4 results this was partly offset by tax credits, which were recognised due to changes in the U.S. tax code during 2019, and Irish R&D tax credits.

The basic loss per share (excluding once-off charges & non-cash financial income) for the year was 19.4 cents versus earnings per share of 11.4 cents in 2018. Meanwhile, there was an unconstrained diluted loss per share of 0.3 cents compared to an EPS of 26.0 cents in 2018.

Earnings before interest, tax, depreciation, amortisation and share option expense (EBITDASO) for the year was $11.0m. This is made up as follows:

	$m
Operating Profit (before non-cash and once-off items)	5.3
Depreciation	2.5
Amortisation	2.4
Share option expense	0.8
EBITDASO	***11.0***

The above measures exclude the impact of an impairment charge of $24.4m net of tax, more information about which is provided below.

Quarter 4 Results

Total revenues for Q4, 2019 were $21.3m, which compares to $24.5m in Q4, 2018 and were broken down as follows:

	2018 Quarter 4	2019 Quarter 4	Increase/ (decrease)
	US$'000	**US$'000**	**%**
Point-of-Care	4,037	2,172	*(46.2)*
Clinical Laboratory	20,487	19,146	*(6.5)*
Total	***24,524***	***21,318***	***(13.1)***

Point-of-Care revenues decreased by 46.2% to $2.2m in Q4, 2019. This was driven by lower HIV sales in both the USA and Africa. The decline in the USA was attributable to the decision to exit this market, which has been in decline for a number of years (see below) whilst African sales were lower due to the normal fluctuations in ordering patterns that characterise that market.

Clinical Laboratory revenues decreased from $20.5m to $19.1m, which represents a decrease of 6.5% compared to Q4, 2018. This decrease was due to lower Infectious Diseases revenues, which included lower Lyme sales due to the migration away from Western Blot testing and lower ELISA sales reflecting the older nature of this technology.

Gross profit for Q4, 2019 amounted to $9.3m equating to a gross margin of 43.5%, which represents an improvement compared to the 41.7% reported in the equivalent quarter last year. This was partly due to the combination of selling price increases and cost savings outweighing the impact of lower revenues and adverse currency movements this quarter.

Research and Development expenses of $1.3m were slightly lower than the equivalent quarter last year ($1.4m) whilst Selling, General and Administrative (SG&A) were also lower for the quarter at $6.4m, which represents a decrease of $0.4m compared to Q4, 2018. Again, these reductions were attributable to cost saving measures, which were implemented earlier in the year.

The combined impact of lower revenues partially offset by an improved gross margin and lower indirect costs resulted in a decrease in operating profit for the quarter from $1.9m to $1.4m.

The profit after tax, before impairment and non-cash financial income, for the quarter was $1.3m compared to $0.8m for the equivalent period last year. This increase was due to an overall tax credit in the quarter of $1.0m mainly due to changes in the U.S. tax code and Irish R&D tax credits.

The basic EPS (excluding once-off charge and non-cash financial income) for the quarter was 6.1 cents versus 3.8 cents in Q4, 2018. Unconstrained diluted EPS for the quarter amounted to 9.0 cents, which compares to 7.0 cents in the equivalent quarter in 2018.

Cash generated from operations during the quarter was $2.4m. Meanwhile interest and taxes paid was $6.0m, which includes payment of the tax settlement that was announced in Q3. Other major cash outflows for the quarter included capital expenditure of $2.3m, payments for property leases of $0.8m and interest payments on our Exchangeable Notes of $2m. Overall, this resulted in a cash balance of $16.4m at the end of the 2019.

Earnings before interest, tax, depreciation, amortisation and share option expense for the quarter was $1.7m.

The above measures exclude the impact of impairment charges amounting to $24.4m net of tax, more details of which are provided below.

Impairment

In accordance with the provisions of accounting standards under IFRS, a company is required to carry out annual impairment reviews 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 $24.4m 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 2018;
- 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, which resulted in a higher cost of capital being attributable to the Company's, expected future cash flows.

Business Developments

Today we are announcing the following developments:

- ***Carlsbad Facility***

  The last number of years have seen a steady migration of customers away from using Western Blot for diagnosing Lyme in favour of alternative testing platforms. Thus, we have seen production volumes at our Carlsbad, California facility (which specialises in Western Blot manufacturing) decline steadily to the extent that it no longer makes economic sense to continue. Consequently, we have taken the decision to close this facility from June 30, 2020. During the period until June 30, we will produce the final batches of Lyme Western Blot for our remaining customers, whilst simultaneously transferring non-Lyme product manufacturing to other group facilities.

- ***USA HIV***

  The reduction in funding for public health HIV testing programs in addition to the CDC's recommendations in favour of fourth generation Antigen testing has led to the decline of our HIV sales in the USA for the last number of years. Volumes had declined to the extent that when manufacturing and marketing costs were taken into account it was no longer an economically viable product. Consequently, in quarter 4 the Company decided to discontinue this product.

The combined impact of withdrawing from the Western Blot Lyme and USA HIV markets will result in a reduction in annual revenues of $4.6m. However, given that these products would have continued to decline we expect that when the associated cost savings are taken into account it will result in a positive impact on annual cash flows of approximately $2m. The Company will be taking a once-off charge for redundancies and other closure costs in relation to the Carlsbad facility in its Q1, 2020 results (the timing of which is determined by accounting rules).

COVID-19

The Company has been working on the development of an ELISA test for the detection of antibodies to the virus that causes COVID-19 in human blood samples. This test will determine which members of the population have had Covid-19 and are therefore now immune and consequently can safely go

back to work and be exposed to the virus e.g. healthcare workers etc. This test will also have utility in monitoring the effectiveness of vaccination programs as vaccines become available. The product, which is substantially complete, is being transferred into manufacturing at our Jamestown, New York facility where production capacity is significant. Trinity will avail of emergency regulatory pathways to expedite the commercialisation of this test across all of its primary markets including the USA and Europe. As already indicated, our production capability is very significant and the instrumentation that can run this ELISA test is freely available in virtually every laboratory in the world.

In addition, the Company is developing a rapid point-of-care Covid-19 test to detect antibodies to the virus that can be run in 12 minutes using one drop of blood procured by finger prick. The utility of this test is similar to that outlined above for the ELISA test. We expect to complete development of this rapid test within the next two months and believe that we can avail of emergency regulatory pathways to expedite the approval for this test in the USA, Europe and other markets.

In terms of the rest of the business, we are currently seeing the following impact of the COVID-19 Pandemic:

- lower testing volumes at our Autoimmune Reference Laboratory in Buffalo - by its nature the testing carried out at this facility is non-acute and hence we are seeing testing being deferred;
- lower levels of instrument placements in our Haemoglobins business as hospitals and other healthcare facilities temporarily defer asset acquisition;
- lower sales of antigens and antibodies through our Fitzgerald business. A significant level of Fitzgerald's revenues are to Chinese diagnostic manufacturers who themselves have seen a reduction in output due to the pandemic and associated lockdown which occurred in certain parts of China. Also Fitzgerald sources a significant portion of its products from China and for similar reasons this has resulted in some supply constraints;
- delays to the completion of the trials for our new HIV screening test, TrinScreen. Testing has been temporarily halted at two of the sites, Kenya and South Africa, which have closed in accordance with local guidelines. Testing at third site has already been completed; and
- growth in demand for our point-of-care respiratory products for Legionnaire's Disease and Strep Pneumoniae.

To date, other than in the case of Fitzgerald, we have not yet experienced any significant supply issues. However, as the pandemic continues we cannot be certain that this will continue to be the case. With this in mind we have been keeping safety stocks of critical raw materials in order to mitigate this risk insofar as is possible.

We expect that revenues will return to more normal levels once the measures that countries are undertaking to tackle the crisis take effect and normality is restored.

Comments

Commenting on the results Kevin Tansley, Chief Financial Officer stated, "Operating profit for the year decreased from $6.7m to $5.3m and was due to a 6.8% fall in revenues. The gross margin for the year, which was 42.2% compared to 42.7% in 2018, was adversely impacted by these lower revenues due to the Company's inherent fixed cost base being spread over lower volumes coupled with adverse currency movements. However, the impact of these two factors was largely offset by the impact of selling price increases and cost savings achieved during the year. Similarly, cost savings contributed to indirect costs falling by $2m during the year.

Our results for Q4, 2019 showed a reduction in operating profit from $1.9m to $1.4m and in this case reflected the impact of lower revenues being partially offset by an improved gross margin and lower indirect costs. This quarter's results also include an impairment charge of $24.4m net of tax which is non-cash in nature and arises due to the accounting requirements governing annual impairment reviews."

Commenting, Ronan O'Caoimh, Chief Executive Officer stated, "Our total revenues for 2019 were $90.4m which compares to $97.0m in 2018. This included lower point-of-care revenues mainly due to lower HIV sales in the USA. Meanwhile, our Clinical Laboratory Revenues fell from $82.2m to $79.0m, mainly due to lower Infectious Diseases (mainly Lyme) in addition to adverse currency movements. However, these decreases were partially offset by growth in our Diabetes and Autoimmunity product lines.

We are extremely conscious of the need for the Company to reach a cash flow breakeven position. With that in mind, we have made two decisions that, whilst negatively affecting future revenues, will have a positive impact on our profitability and cash flows. Firstly, we have exited the HIV point-of-care market in the USA. For a number of years, this market has been declining as the funding for federal testing programmes has contracted, to such an extent that it no longer made economic sense for us to continue serving this market.

Secondly, we have made the decision to close our manufacturing plant in Carlsbad, California on June 30, 2020. We were faced with a scenario whereby the continual migration away from Western Blot testing for Lyme in favour of other platforms resulted in this plant becoming economically unviable. We are now making our final batches of Lyme products and transferring the remaining Carlsbad manufactured products to other sites within the group.

Finally, we are beginning to see some negative impact on our revenues due to the COVID-19 pandemic. This will have an impact on our quarter 1 revenues and more so in quarter 2. Whilst it is not possible to be certain how long the current conditions will last, we expect that the impact will be short term in nature and that when normality resumes the nature of our business is such that we expect revenues to rebound quickly and for there to be no long term impact. Trinity is pleased to be announcing today that it is close to completing the development of an ELISA test for the detection of antibodies to the virus that causes COVID-19. This will be followed by a Rapid antibody test soon thereafter. These tests will be launched in all of our major markets in an expedited manner by availing of emergency regulatory pathways."

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. In addition, there is uncertainty about the spread of the COVID19 virus and the impact it will have on the Company's operations, the demand for Company's products, global supply chains and economic activity in general. These and other risks and uncertainties are detailed in the Company's Securities and Exchange Commission filings.

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 Dec 31, 2019 (unaudited)	Three Months Ended Dec 31, 2018 (unaudited)	Year Ended Dec 31, 2019 (unaudited)	Year Ended Dec 31, 2018 (unaudited)
Revenues	**21,318**	**24,524**	**90,435**	**97,035**
Cost of sales	(12,044)	(14,290)	(52,315)	(55,586)
Gross profit	**9,274**	**10,234**	**38,120**	**41,449**
Gross profit %	*43.5%*	*41.7%*	*42.2%*	*42.7%*
Other operating income	24	26	91	102
Research & development expenses	(1,332)	(1,386)	(5,325)	(5,369)
Selling, general and administrative expenses	(6,399)	(6,752)	(26,852)	(28,164)
Indirect share based payments	(123)	(205)	(732)	(1,335)
Operating profit	**1,444**	**1,917**	**5,302**	**6,683**
Financial income	88	158	464	735
Financial expenses	(1,239)	(1,012)	(4,945)	(4,391)
Net financing expense	(1,151)	(854)	(4,481)	(3,656)
Profit before tax, non-cash & once-off items	**293**	**1,063**	**821**	**3,027**
Income tax (expense) / credit	988	(271)	(4,887)	(637)
Profit / (loss) after tax before non-cash & once-off items	**1,281**	**792**	**(4,066)**	**2,390**
Non-cash financial (expense) / income	(160)	431	(405)	700
Impairment & once-off items (net of tax)	(24,443)	(25,180)	(24,443)	(25,180)
Loss after tax and once-off items	**(23,322)**	**(23,957)**	**(28,914)**	**(22,090)**
Loss per ADR (US cents)	(111.6)	(114.6)	(138.3)	(105.7)
Earnings per ADR (US cents)**	6.1	3.8	(19.4)	11.4
Diluted loss per ADR (US cents)	(87.0)*	(91.8)*	(96.2)*	(71.3)*
Diluted earnings per ADR (US cents)**	9.0*	7.0*	(0.3)*	26.0*
Weighted average no. of ADRs used in computing basic earnings per ADR	20,901,703	20,901,703	20,901,703	20,903,227
Weighted average no. of ADRs used in computing diluted earnings per ADR	25,467,516	25,467,516	25,467,516	25,877,205

* 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 impairment, once-off charges & non-cash financial items.

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 and some items included in income tax are non-GAAP accounting presentations.

Trinity Biotech plc
Consolidated Balance Sheets

	Dec 31, 2019 US$ '000 (unaudited)	Sept 30, 2019 US$ '000 (unaudited)	June 30, 2019 US$ '000 (unaudited)	Dec 31, 2018 US$ '000 (unaudited)
ASSETS				
Non-current assets				
Property, plant and equipment	9,290	26,306	26,293	5,362
Goodwill and intangible assets	43,654	57,948	56,079	52,951
Deferred tax assets	6,252	7,339	6,744	5,703
Other assets	485	555	591	558
Total non-current assets	59,681	92,148	89,707	64,574
Current assets				
Inventories	32,021	29,960	31,487	30,359
Trade and other receivables	20,987	24,811	24,333	24,441
Income tax receivable	1,982	1,243	1,187	1,584
Cash, cash equivalents and deposits	16,400	25,090	24,990	30,277
Total current assets	71,390	81,104	81,997	86,661
TOTAL ASSETS	131,071	173,252	171,704	151,235
EQUITY AND LIABILITIES				
Equity attributable to the equity holders of the parent				
Share capital	1,224	1,213	1,213	1,224
Share premium	16,187	16,187	16,187	16,187
Accumulated surplus	11,514	50,462	50,151	24,368
Other reserves	(24,212)	(28,930)	(28,479)	2,275
Total equity	4,713	38,932	39,072	44,054
Current liabilities				
Income tax payable	48	5,717	5,885	210
Trade and other payables	19,351	20,135	18,472	17,344
Provisions	50	50	50	50
Total current liabilities	19,449	25,902	24,407	17,604
Non-current liabilities				
Exchangeable senior note payable	82,025	81,865	81,793	81,620
Other payables	17,745	17,803	18,351	526
Deferred tax liabilities	7,139	8,750	8,081	7,431
Total non-current liabilities	106,909	108,418	108,225	89,577
TOTAL LIABILITIES	126,358	134,320	132,632	107,181
TOTAL EQUITY AND LIABILITIES	131,071	173,252	171,704	151,235

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 Dec 31, 2019 (unaudited)	Three Months Ended Dec 31, 2018 (unaudited)	Year Ended Dec 31, 2019 (unaudited)	Year Ended Dec 31, 2018 (unaudited)
Cash and cash equivalents at beginning of period	**25,090**	**35,679**	**30,277**	**57,607**
Operating cash flows before changes in working capital	2,703	3,168	12,198	13,075
Changes in working capital	(321)	(2,939)	(796)	(7,596)
Cash generated from operations	2,382	229	11,402	5,479
Net Interest and Income taxes received/(paid)	(5,962)	1,406	(5,928)	1,456
Capital Expenditure & Financing (net)	(2,325)	(5,039)	(12,295)	(17,286)
Payments for leases (IFRS 16)[1]	(787)	-	(3,060)	-
Free cash flow	(6,692)	(3,404)	(9,881)	(10,351)
Share buyback	-	-	-	(434)
Once-off items	-	-	-	(12,042)
30 year Exchangeable Note interest payment	(1,998)	(1,998)	(3,996)	(4,503)
Cash and cash equivalents at end of period	**16,400**	**30,277**	**16,400**	**30,277**

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).

[1] Payments for leases relates to leases accounted for as operating leases in the prior year(s).