Trinity Biotech Announces Quarter 4 and Fiscal Year 2020 Financial Results

DUBLIN, Ireland, March 25, 2021 — 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, 2020 and fiscal year 2020.

Fiscal Year 2020 Results

Total revenues for fiscal year 2020 were $102m versus $90.4m in 2019, an increase of 12.8% year on year and were broken down as follows:

	Full Year 2019 US$'000	**Full Year 2020 US$'000**	**Increase/ (decrease) %**
Point-of-Care	11,393	9,215	(19.1%)
Clinical Laboratory	79,042	92,765	17.4%
Total	**90,435**	**101,980**	**12.80%**

Point-of-Care revenues decreased from $11.4m in 2019 to $9.2m in 2020, which represents a decrease of 19.1%. 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 in 2019, which had been in decline for a number of years, whilst African sales were lower due to logistical and testing constraints arising from Covid-19 in the second and third quarters, with normal trading patterns only being restored in Q4 2020.

Clinical Laboratory revenues increased from $79.0m in 2019 to $92.8m, which represents an increase of 17.4%. The increase is mainly due to strong sales within our Covid-19 related portfolio of products, with our PCR Viral Transport Media product being the most significant contributor to revenue within that portfolio.

Due mainly to the impact of Covid-19, revenues for Haemoglobins, Autoimmune and Infectious Disease products all recorded decreases in 2020 compared to 2019. In our Haemoglobins business, revenues were affected by the deferral of Diabetes instrument purchases as healthcare resources were stretched by the pandemic. Our Autoimmune business was also impacted by Covid-19, experiencing lower testing volumes at its New York reference laboratory. Infectious Diseases revenues were impacted not only by pandemic factors but also by lower Lyme sales attributable to the continued migration away from Western Blot to other testing formats.

The gross margin for the year was 47.6% compared to 42.2% in 2019. This increase was largely due to the impact of strong sales within our Covid-19 related portfolio of products, fewer instrument placements, lower depreciation and a range of cost saving measures put in

place during the year.

Other operating income increased from $0.1m in 2019 to $1.9m in 2020. The $1.9m income in 2020 mainly relates to funding received under the U.S. government's Cares Act, principally its Paycheck Protection Program. Two out of six Paycheck Protection Program ("PPP") loans received by the Company were forgiven during the year. We are in the process of seeking forgiveness for the remaining four PPP loans totalling $2.9m and we expect them to be forgiven in 2021. These four remaining loans are treated as short term liabilities at December 31, 2020.

Research and Development expenses showed a slight reduction from $5.3m to $5.1m year on year. Meanwhile, Selling General and Administrative (SG&A) expenses decreased from $26.9m to $24.2m, a decrease of 10.0%. The decrease in SG&A expenses was mainly driven by cost saving measures which were implemented in response to the pandemic, and included the furloughing of some employees, reduced travel costs and cancellation of trade shows and other marketing activities. These savings were partially offset by increased performance-related pay due to higher revenues and profits.

Operating profit (before the impact of once-off items) for the year increased from $5.3m reported in 2019 to $20.3m in 2020. This increase was mainly attributable to higher revenues and gross margin, a reduction in indirect costs and the receipt of government financial aid.

The net financing expense for the year increased from $4.5m to $4.9m mainly due to lower deposit interest income on account of lower amounts held on deposit and lower prevailing interest rates.

Profit before tax (before the impact of once-off items & non-cash financial expense) for 2020 was $15.5m, an increase of $14.7m versus the $0.8m reported 2019. In 2020 the Company recorded an overall tax credit of $0.2m due to the impact of R&D tax credits in USA, Canada and Ireland.

Meanwhile, there was a profit after tax (before the impact of once-off items & non-cash financial income) of $15.7m in 2020 compared to a reported loss of $4.1m in 2019.

A non-cash financial expense of $1.9m was recognised in relation to the Exchangeable Notes. This was due to a non-cash interest charge of $0.7m and a non-cash charge of $1.2m arising due to an increase in the fair value of the derivatives embedded in these notes.

The basic earnings per ADR (our equivalent to EPS) (excluding once-off charges & non-cash financial items) for the year was 75.0 cents versus a loss per ADR of 19.4 cents in 2019. Meanwhile, there was an unconstrained diluted earnings (excluding once-off charges & non-cash financial items) per ADR of 74.9 cents compared to a loss per ADR of 0.3 cents in 2019.

Earnings before interest, tax, depreciation, amortisation and share option expense

(EBITDASO) for the year was $24.2m. This is made up as follows:

	$m
Operating Profit (before non-cash and once-off items)	20.3
Depreciation	1.7
Amortisation	1.4
Share option expense	0.8
EBITDASO	***24.2***

The above measures exclude the impact of an impairment charge of $17.8m net of tax, more information about which is provided below and a provision of $2.4m relating to the closure of our Carlsbad, CA facility in Q2 2020.

Quarter 4 Results

Total revenues for Q4, 2020 were $32.8m, which compares to $21.3m in Q4, 2019 and were broken down as follows:

	2019 Quarter 4 US$'000	**2020 Quarter 4 US$'000**	**Increase/ (decrease) %**
Point-of-Care	2,172	2,548	17.3%
Clinical Laboratory	19,146	30,217	57.8%
Total	***21,318***	***32,765***	***53.70%***

Point-of-Care revenues in Q4, 2020 were higher than Q4, 2019 and in both quarters are largely comprised of sales of our Unigold HIV test in Africa. There was a strong recovery in HIV revenues in Africa this quarter following two successive quarters that were adversely affected by Covid-19 restrictions.

Clinical Laboratory revenues increased from $19.1m to $30.2m, which represents an increase of 57.8% compared to Q4, 2019. This increase is mainly due to strong sales within our Covid-19 related portfolio of products, with our PCR Viral Transport Media continuing to be the most significant contributor to revenue within that portfolio. The recovery in the Company's other product lines that we reported in Q3 2020 continued into Q4 2020. However, as expected revenues in Q4, 2020 did not return fully to pre-Covid levels mainly due to lower testing volumes at our Autoimmunity reference laboratory in New York and lower demand for some infectious disease testing outside of Covid-19.

Gross profit for Q4, 2020 amounted to $15.7m equating to a gross margin of 47.8%, which represents an improvement compared to the 43.5% reported in the equivalent quarter last year. This increase was largely due to the sales mix (more Covid-19 related revenues and fewer instrument placements) and cost saving measures.

Other operating income increased from $0.02m in Q4 2019 to $1.9m in Q4 2020. The $1.9m income in 2020 mainly relates to funding received under the U.S. government's Cares Act, principally its Paycheck Protection Program. Two out of six Paycheck Protection Program ("PPP") loans received by the Company were forgiven during the year. As mentioned above, we are in the process of seeking forgiveness for the remaining four PPP loans totalling $2.9m and we expect them to be forgiven in 2021. These four remaining loans are treated as short term liabilities at December 31, 2020.

Research and Development expenses remained stable at $1.3m whilst Selling, General and Administrative (SG&A) expenses were higher for the quarter at $6.9m, which represents an increase of just under $0.5m compared to Q4, 2019. The increase in SG&A expenses was mainly driven by higher performance-related pay and unrealised foreign exchange losses on non-US Dollar denominated lease liabilities.

Operating profit (before the impact of once-off items) increased from $1.4m to $9.1m for the quarter, representing more than six times the operating profit for the same period last year. This was due to the impact of higher revenues, improved gross margin and Paycheck Protection Program loans forgiven, partially offset by higher indirect expenses during the quarter.

Financial income for the quarter showed a reduction due to lower average cash on deposit and interest rates. Meanwhile, Financial Expenses amounted to $1.2m, which was broadly in line with Q4, 2019. Of this, $1.0m related to interest payable on the Company's Exchangeable Notes, with the remaining $0.2m representing notional financing charges arising on leased assets. A further non-cash expense of $0.8m was recognised in this quarter's income statement, again in relation to the Exchangeable Notes. This was due to a non-cash interest charge of $0.2m and a loss of $0.6m arising due to an increase in the fair value of the derivatives embedded in these notes.

The profit after tax, before impairment and non-cash financial expense, for the quarter was $8.6m compared to $1.3m for the equivalent period last year.

The basic earnings per ADR (our equivalent to EPS) (excluding once-off charge and non-cash financial items) for the quarter was 41.0 cents versus 6.1 cents in Q4, 2019. Unconstrained diluted earnings (excluding once-off charges & non-cash financial items) per ADR for the quarter amounted to 35.9 cents, which compares to 9.0 cents in the equivalent quarter in 2019.

Earnings before interest, tax, depreciation, amortisation and share option expense for the quarter was $10.1m. This is made up as follows:

	$m
Operating Profit (before non-cash and once-off items)	9.1

Depreciation	0.5
Amortisation	0.2
Share option expense	0.3
EBITDASO	***10.1***

The above measures exclude the impact of impairment charges amounting to $17.8m net of tax. More details on the impairment are provided below.

Cash generated from operations during the quarter was $17.3m. Meanwhile the Company paid $2m interest on the Exchangeable Notes. Other major cash outflows for the quarter included taxes and other interest of $1.1m, capital expenditure of $3.6m and payments for property leases of $0.7m. Overall, this resulted in an increase in cash from $19.9m to $27.3m, an increase of $7.4m during the quarter.

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 $17.8m net of tax being recognised. A number of factors impacted this calculation including the Company's share price at 31 Dec 2020, cost of capital, cash flow projections and net asset values across each of the Company's individual main business lines.

New Product Update

HIV Point of Care Screening – TrinScreen

Despite the impact of Covid-19 on HIV testing in Africa, the Company has successfully completed the necessary clinical trials for submission to the World Health Organisation ("WHO") for pre-qualification of our HIV screening product, TrinScreen. This product, once approved, will allow the Company to build on its strong presence in HIV testing in Africa, with the Company having been the main confirmatory test provider over many years. The Company expects to submit the pre-qualification application to the WHO before the end of March 2021. While it is expected that the WHO will take several months to consider the approval, the Company intends to use that time to prepare for manufacturing of the test at our highly-automated facility in Ireland.

Covid-19 Rapid Antibody Test

Development of the Company's Covid-19 rapid anti-body test has been completed. The Company has begun to manufacture product for final validation in advance of an Emergency Use Authorisation ("EUA") submission to the FDA. The Company expects to submit an EUA application to the FDA during quarter 2, 2021 to allow for its sale in the USA.

Covid-19 Rapid Antigen Test

The Company is developing a rapid Covid-19 antigen test. The Company intends to leverage its existing rapid infectious disease test design to expedite the development and validation timeframe and also generate scale efficiencies in manufacture & distribution.

Comments

Commenting on the results John Gillard, Chief Financial Officer stated, "The Company delivered another strong quarter with an operating profit, excluding impairment charges, of $9.1m, compared to $1.4m in Q4 2019. Gross margin for the quarter increased to 47.8% compared to 43.5% in Q4 2019, with the company benefiting from a positive sales mix and cost control measures put in place during the year."

Commenting, Ronan O'Caoimh, Chief Executive Officer stated, "We are pleased to have such a profitable quarter with a 54% increase in sales compared to Q4 2019, largely driven by strong sales within our Covid-19 related portfolio of products. It is also encouraging to see the continued rebound of our core business into Q4 2020. This strong financial performance has translated into a closing cash balance of $27.3m, an increase of over $7m in the quarter. We are also excited to have completed the necessary clinical trials for our new HIV screening test, TrinScreen and look forward to an expected pre-qualification submission to the WHO by the end of this month. We expect that once the product is approved by the WHO, the Company is ideally positioned to take a significant share of the HIV screening market in Africa given the excellent clinical performance of the product and the Company's strong existing reputation in the HIV testing market in Africa, earned over many years."

Once-off charges and some items included in income tax are non-GAAP accounting presentations. The above mentioned numbers are unaudited.

Certain statements made in this release that are not historical are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The words "estimate", "project", "intend", "expect", "believe" and similar expressions are intended to identify forward-looking statements. These forward-looking statements involve known and unknown risks and uncertainties. Many factors could cause the actual results, performance or achievements of Trinity Biotech to be materially different from any future results, performance or achievements that may be expressed or implied by such forward-looking statements, including, but not limited to, the results of research and development efforts, risks associated with the outbreak and global spread of the coronavirus (COVID-19), the effect of regulation by the U.S. Food and Drug Administration and other agencies, the impact of competitive products, product development commercialization and technological difficulties. For additional information regarding these and other risks and uncertainties associated with Trinity Biotech's business, reference is made to our reports filed from time to time with the U.S. Securities and Exchange Commission. We undertake no obligation to

update or revise any forward-looking statements for any reason.

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, 2020 (unaudited)**	**Three Months Ended Dec 31, 2019 (unaudited)**	**Year Ended Dec 31, 2020 (unaudited)**	**Year Ended Dec 31, 2019 (unaudited)**
Revenues	**32,765**	**21,318**	**101,980**	**90,435**
Cost of sales	(17,108)	(12,044)	(53,400)	(52,315)
Gross profit	**15,657**	**9,274**	**48,580**	**38,120**
Gross profit %	*47.8%*	*43.5%*	*47.6%*	*42.2%*
Other operating income	1,841	24	1,860	91
Research & development expenses	(1,284)	(1,332)	(5,080)	(5,325)
Selling, general and administrative expenses	(6,872)	(6,399)	(24,234)	(26,852)
Indirect share based payments	(276)	(123)	(780)	(732)
Operating profit	**9,066**	**1,444**	**20,346**	**5,302**
Financial income	–	88	36	464
Financial expenses	(1,224)	(1,239)	(4,892)	(4,945)
Net financing expense	(1,224)	(1,151)	(4,856)	(4,481)
Profit before tax, non-cash & once-off items	**7,842**	**293**	**15,490**	**821**
Income tax credit/(expense)	730	988	182	(4,887)
Profit / (loss) after tax before non-cash & once-off items	**8,572**	**1,281**	**15,672**	**(4,066)**
Non-cash financial expense	(820)	(160)	(1,859)	(405)
Impairment & once-off items (net of tax)	(17,776)	(24,443)	(20,201)	(24,443)
Loss after tax and once-off items	**(10,024)**	**(23,322)**	**(6,388)**	**(28,914)**
Earnings/(Loss) per ADR (US cents)	(48.0)	(111.6)	(30.6)	(138.3)
Earnings/(Loss) per ADR (US cents)**	41.0	6.1	75.0	(19.4)
Diluted earnings/(loss) per ADR (US cents)	(30.8)*	(87.0)*	(2.0)*	(96.2)*
Diluted earnings/(loss) per ADR (US cents)**	35.9	9.0*	74.9	(0.3)*
Weighted average no. of ADRs used in computing basic earnings per ADR	20,901,703	20,901,703	20,901,703	20,901,703
Weighted average no. of ADRs used in computing diluted earnings per ADR	26,663,066	25,467,516	26,256,183	25,467,516

* 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, 2020 US$ '000 (unaudited)	Sept 30, 2020 US$ '000 (unaudited)	June 30, 2020 US$ '000 (unaudited)	Dec 31, 2019 US$ '000 (unaudited)
ASSETS				
Non-current assets				
Property, plant and equipment	8,547	9,462	9,297	9,290
Goodwill and intangible assets	33,860	47,876	46,751	43,654
Deferred tax assets	4,185	5,981	6,613	6,252
Other assets	355	387	378	485
Total non-current assets	46,947	63,706	63,039	59,681
Current assets				
Inventories	30,219	29,607	31,473	32,021
Trade and other receivables	22,668	21,658	17,048	20,987
Income tax receivable	3,086	1,194	1,598	1,982
Cash and cash equivalents	27,327	19,910	15,570	16,400
Total current assets	83,300	72,369	65,689	71,390
TOTAL ASSETS	130,247	136,075	128,728	131,071
EQUITY AND LIABILITIES				
Equity attributable to the equity holders of the parent				
Share capital	1,224	1,213	1,224	1,224
Share premium	16,187	16,187	16,187	16,187
Accumulated surplus	5,918	15,665	8,194	11,514
Other reserves	(25,548)	(25,994)	(26,317)	(24,212)
Total equity	(2,219)	7,071	(712)	4,713
Current liabilities				
Income tax payable	154	765	373	48
Trade and other payables	26,488	22,281	22,327	19,351
Provisions	416	50	50	50
Total current liabilities	27,058	23,096	22,750	19,449
Non-current liabilities				
Exchangeable senior note payable	83,884	83,063	82,902	82,025
Other payables	16,619	16,786	16,531	17,745
Deferred tax liabilities	4,905	6,059	7,257	7,139
Total non-current liabilities	105,408	105,908	106,690	106,909
TOTAL LIABILITIES	132,466	129,004	129,440	126,358
TOTAL EQUITY AND LIABILITIES	130,247	136,075	128,728	131,071

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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). Some items included in equity are non-GAAP accounting presentations.

Trinity Biotech plc
Consolidated Statement of Cash Flows

(US$000's)	**Three Months Ended Dec 31, 2020 (unaudited)**	**Three Months Ended Dec 31, 2019 (unaudited)**	**Year Ended Dec 31, 2020 (unaudited)**	**Year Ended Dec 31, 2019 (unaudited)**
Cash and cash equivalents at beginning of period	**19,910**	**25,090**	**16,400**	**30,277**
Operating cash flows before changes in working capital	7,103	2,703	20,604	12,198
Changes in working capital	10,164	(321)	7,688	(796)
Cash generated from operations	17,267	2,382	28,292	11,402
Net Interest and Income taxes received/(paid)	(1,142)	(5,962)	(886)	(5,928)
Capital Expenditure & Financing (net)	(3,615)	(2,325)	(10,435)	(12,295)
Payments for leases (IFRS 16)	(670)	(787)	(3,031)	(3,060)
Free cash flow	11,840	(6,692)	13,940	(9,881)
Payment of HIV/2 License Fee	–	–	(1,112)	–
Once-off items	(2,425)	–	(2,425)	–
30 year Exchangeable Note interest payment	(1,998)	(1,998)	(3,996)	(3,996)
Proceeds received under Paycheck Protection Program	–	–	4,520	–
Cash and cash equivalents at end of period	**27,327**	**16,400**	**27,327**	**16,400**

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).

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