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Trinity Biotech Announces Quarter 4 and Fiscal Year 2021 Financial Results

DUBLIN, Ireland (April 11, 2022).... 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, 2021 and fiscal year 2021.

Fiscal Year 2021 Results

Total revenues for fiscal year 2021 were \$93.0m compared to \$102.0m in 2020, a decrease of 8.8% year on year and were broken down as follows:

	Full Year 2020	Full Year 2021	Increase/ (decrease)
	US\$'000	US\$'000	%
Point-of-Care	9,215	10,337	12.2%
Clinical Laboratory	92,765	82,628	(10.9%)
Total	101,980	92,965	(8.8%)

Point-of-Care revenues increased from \$9.2m in 2020 to \$10.3m in 2021, which represents an increase of 12.2%. This was driven by higher HIV sales in Africa. In 2020, HIV revenues were negatively impacted by logistical and testing constraints arising from COVID-19. Non-HIV point-of-care revenues, which mainly comprise a syphilis test sold in USA, were broadly unchanged year on year.

Clinical Laboratory revenues decreased from \$92.8m in 2020 to \$82.6m in 2021, which represents a decrease of 10.9%. The decrease is mainly due to lower sales of our PCR Viral Transport Media (“VTM”). In 2020, demand for VTM products was exceptional while there was limited worldwide manufacturing capacity. As the pandemic has persisted, manufacturing capacity has ramped up significantly with a consequent negative impact on selling prices.

As stated previously, the Company noted a significant reduction in demand for new orders of VTM from early 2021 as COVID-19 testing volumes dropped and customers utilised stockpiled product. While the situation relating to COVID-19 products remains very fluid, with the evolving impact of the new variants the Company has seen increased customer interest in VTM products over recent months and has resumed manufacturing VTM products, albeit in lower volumes compared to late 2020. The Company has retained the capability to flex manufacturing volumes should market conditions warrant it.

In 2021, there was a partial return towards more normalised level of Haemoglobins testing. While COVID-19 public health restrictions remained in place in 2021 in many markets, these restrictions were not as severe as in 2020. As a result, diabetic related testing revenues increased 16% in 2021 and we are continuing to see increasing demand for these instruments and consumables as diabetic testing programmes continue their return to normalisation.

Also, within Clinical Laboratory, our life science raw materials business, Fitzgerald and our clinical chemistry product line both recorded single digit revenue growth in 2021.

Our autoimmune revenues decreased by 1% compared to 2020, primarily due to lower revenues in our reference laboratory. This relates to our New York reference laboratory which offers laboratory-testing services for autoimmune disorders, such as Sjogren's syndrome, hearing loss, celiac disease, lupus, rheumatoid arthritis, and systemic sclerosis. While revenues for our proprietary Sjogren's syndrome test increased by 46% compared to 2020 these were offset by a reduction in testing for other disorders due to fewer patients visiting their physicians for pandemic reasons and also due to the ending of certain testing that was carried out for a high-volume customer. We expect demand for Sjogren's testing to continue to grow as there appears to be commonality between Sjogren's symptoms and Long COVID symptoms. In addition, we continue to focus on expanding the range of tests available at the reference lab, including testing panels specifically aimed at autoimmune conditions associated with Long COVID.

The gross margin for the year was 41.0% compared to 47.6% in 2020. Gross margin remains susceptible to product mix changes, geographic spread, currency fluctuations and product level variation. The reduction in the gross margin in 2021 compared to 2020 is mainly due to comparatively higher sales prices for VTM in 2020 caused by exceptionally high demand with prices and consequently gross margin reducing progressively during 2021. Lower margins were also recorded in our Fitzgerald life sciences supply business in 2021 compared to 2020 as the company made a strategic decision to pursue larger volume orders that typically have lower pricing but are expected to add to overall profitability. Additionally, the receipt of government payroll supports in 2020 related to COVID-19 helped to increase the gross margin in 2020 and these supports are not being claimed in 2021.

Other operating income increased from \$1.9m in 2020 to \$4.7m in 2021. In both years, this income almost entirely comprises income received under the U.S. government's Cares Act, principally its Paycheck Protection Program ("PPP") and its Provider Relief Fund. All PPP loans received in 2020 and in 2021 have now been 100% forgiven by the U.S. government. Four PPP loans received in 2020, but not forgiven until 2021, totalling \$2.9m, were treated as short term liabilities at December 31, 2020.

Research and Development expenses decreased from \$5.1m in 2020 to \$4.5m in 2021. This reduction is mainly due to the closure of our Western Blot R&D facility in California in June 2020 and a continued focus on cost control. Selling General and Administrative (SG&A) expenses decreased from \$24.2m to \$23.4m, a decrease of 3.6%. In 2020, SG&A expenses were unusually low due to certain non-recurring savings, principally the furloughing of employees because of the pandemic and government payroll supports related to COVID-19. Despite neither of these savings occurring in 2021, a reduction in SG&A costs was recorded due to a cost saving program which saw SG&A headcount reduced by 7%.

Operating profit (before the impact of once-off items) for the year decreased from \$20.3m reported in 2020 to \$13.8m in 2021. This decrease is mainly attributable to lower revenues and gross margin, partially offset by lower indirect costs and the recognition of a higher amount of PPP loan forgiveness.

The net financing expense for the year decreased by 1.0% to \$4.8m mainly due to lower non-cash interest expense relating to lease liabilities for right-of-use assets.

Profit before tax (before the impact of once-off items & non-cash financial income/expense) for 2021 was \$9.0m, a decrease of \$6.5m versus the \$15.5m reported 2020. In 2021 the Company recorded an overall tax credit of \$0.2m due to the impact of R&D tax credits in the USA, Canada and Ireland.

Profit after tax (before the impact of once-off items & non-cash financial income/expense) was \$9.2m in 2021 compared to \$15.7m in 2020.

A non-cash financial income of \$0.6m was recognised in relation to the Exchangeable Notes. This was due to non-cash financial income of \$1.2m arising from a decrease in the fair value of the derivatives embedded in these notes, partially offset by an accretion interest charge of \$0.6m on the Exchangeable Notes.

In 2021 the Company incurred impairment charges and once-off items of \$8.9m. This results in a profit after tax of \$0.9m compared to a loss of \$6.4m in 2020.

The basic earnings per ADR for the year was 4.2 cents versus a loss of 30.6 cents in 2020. Meanwhile, there was an unconstrained diluted earnings per ADR of 16.1 cents compared to a loss per ADR of 2.0 cents in 2020.

Earnings before interest, tax, depreciation, amortisation and share option expense for the year and excluding the impact of once-off items, non-cash financial income/expenses and fair value movements for the year (Adjusted EBITDASO) was \$17.7m. This is made up as follows:

	\$m
Profit after tax	0.9
Non-cash financial income	(0.6)
Impairment & once-off items	8.9
Net financing expense	4.8
Income tax	(0.2)
Operating Profit (before non-cash and once-off items)	13.8
Depreciation	1.9
Amortisation	0.9
Adjusted EBITDA	16.6
Share option expense	1.1
Adjusted EBITDASO	17.7

Impairment and once-off items include the following:

	2021 \$m
Impairment loss (IAS 36)	7.0
Loan origination costs	1.6
Restructuring expenses	0.3
Total	8.9

More details on these items are provided below.

Quarter 4 Results

Total revenues for Q4, 2020 were \$32.8m, which compares to \$19.5m in Q4, 2021 and were broken down as follows:

	2020 Quarter 4 US\$'000	2021 Quarter 4 US\$'000	Increase/ (decrease) %
Point-of-Care	2,548	2,379	(6.6%)
Clinical Laboratory	30,217	17,146	(43.3%)
Total	32,765	19,525	(40.4%)

Point-of-Care revenues in Q4, 2021 were 6.6% lower than Q4, 2020 and in both quarters are largely comprised of sales of our Unigold HIV test in Africa.

Clinical Laboratory revenues decreased from \$30.2m to \$17.1m, which represents a decrease of 43.3% compared to Q4, 2020. The decrease is mainly due to lower revenues from our PCR VTM products. In Q4 2020, demand for PCR VTM products was exceptional while there was limited worldwide manufacturing capacity. As the pandemic has persisted, manufacturing capacity has ramped up significantly with a consequent negative impact on selling prices.

Gross profit for Q4, 2021 amounted to \$7.2m equating to a gross margin of 37.1%, compared to the 47.8% reported in the equivalent quarter last year. The reduction in gross margin is mainly due to the exceptionally strong sales and margins recorded in Q4 2020 within our COVID-19 related portfolio of products, with pricing and thus margin falling as 2021 progressed. Sales mix within Point-Of-Care also had a negative impact on gross margin in Q4 2021 compared to Q4 2020.

Other operating income decreased from \$1.8m in Q4 2020 to \$0.7m in Q4 2021. In both quarters, this income almost entirely comprises income received under the U.S. government's Cares Act, principally its PPP and its Provider Relief Fund. The \$0.7m recorded in Q4 2021 represents the sixth and final PPP loan recognised as income. As a result, there are no remaining PPP loans treated as short term liabilities at December 31, 2021.

Research and Development expenses reduced from \$1.3m in Q4 2020 to \$0.9m in Q4 2021 due to a continued focus on cost control measures. Selling, General and Administrative (SG&A) expenses reduced by \$1.7m to \$5.2m. The decrease in SG&A expenses was mainly driven by a foreign exchange loss recorded in Q4 2020 on non-US Dollar denominated lease liabilities, whereas the equivalent movement in Q4 2021 was a foreign exchange gain; lower performance-related pay and the closing out of certain claims against the company at a lower amount than was reserved.

Operating profit (before the impact of once-off items) decreased from \$9.1m to \$1.7m for the quarter. This decrease is mainly attributable to lower revenues and gross margin, a lower amount of government financial aid recognised as other operating income, partially offset by lower indirect costs.

Financial Expenses amounted to \$1.2m, which was broadly in line with Q4, 2020. 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 almost \$0.2m was recognised in this quarter's income statement, again in relation to the Exchangeable Notes.

In Q4, 2021 the Company recorded an overall tax credit of \$1.2m compared to a credit of \$0.7m in Q4 2020, with this increase primarily related to the attribution of income to lower tax jurisdictions.

The profit after tax, before impairment and non-cash financial expense, for the quarter was \$1.7m compared to \$8.6m for the equivalent period last year.

In Q4, 2021 the Company incurred impairment charges and once-off items of \$2.8m. This results in a loss after tax of \$1.3m compared to a loss of \$10m in Q4 2020

The basic earnings per ADR for the quarter was a loss of 6 cents versus a loss of 48 cents in Q4 2020. Unconstrained diluted loss per ADR for the quarter amounted to a loss of 0.4 cents, which compares to a loss per ADR of 30.8 cents in the equivalent quarter in 2020.

Earnings before interest, tax, depreciation, amortisation and share option expense for the quarter and excluding the impact of once-off items, non-cash financial income/expenses and fair value movements (Adjusted EBITDASO) was \$2.4m. This is made up as follows:

	\$m
Loss after tax	(1.3)
Non-cash financial expense	0.2
Impairment & once-off items	2.8
Net financing expense	1.2
Income tax	(1.2)
Operating Profit (before non-cash and once-off items)	1.7
Depreciation	0.3
Amortisation	0.2
Adjusted EBITDA	2.2
Share option expense	0.2
Adjusted EBITDASO	2.4

Impairment & once-off items include the following:

	Q4 2021 \$m
Impairment loss (IAS 36)	0.9
Loan origination costs	1.6
Restructuring expenses	0.3
Total	2.8

- *Impairment loss* - in accordance with the provisions of IFRS accounting standards, a company is required to carry out periodic impairment reviews in order to determine the appropriate carrying value of its net assets. The impairment review performed at December 31, 2021 has resulted in a non-cash impairment charge of \$0.9m being recognised. In Q2, 2021, an impairment loss of \$6.1m was also recognised. A number of factors impacted the impairment review at year end including the Company's share price at 31 December 2021, cost of capital, cash flow projections and net asset values across each of the Company's individual cash generating units.
- *Loan origination costs* – as previously announced, the Company and its subsidiaries entered into a \$81,250,000 senior secured term loan credit facility with Perceptive Advisors in December 2021. In Q4 2021, loan origination costs of \$1.6m were incurred, comprising loan commitment and professional fees. These costs have been expensed in the Income Statement, as the loan was subject to shareholder approval and that approval was not received until post year end.
- *Restructuring expenses* – as part of the Company's ongoing focus on automation, efficiency and cost savings in Q4 2021, a restructuring program was implemented in the Company's Irish manufacturing facility. A voluntary redundancy program resulted in a 7% reduction of the workforce. Restructuring expenses comprise termination payments, all of which were paid before December 31, 2021.

Cash flows

Cash generated from operations during the quarter was \$3.9m. Meanwhile the Company paid \$2m interest on the Exchangeable Notes. Other major cash outflows for the quarter included capital expenditure of \$2.4m and payments for property leases of \$0.7m. Overall, this resulted in a decrease in cash from \$27.5m to \$25.9m, a decrease of \$1.6m during the quarter. In Q4 2021, the Company paid \$0.8m in relation to refinancing closing fees.

Q4 2021 Earnings Conference Call

The Company has scheduled a conference call for Monday April 11, 2022 at 11:00am ET (4:00pm GMT) to discuss the results of the quarter.

Interested parties can access the call by dialling:

US Toll Free: 1-844-861-5499

International Toll: 1-412-317-6581

Ireland Toll: 014311269

Ireland Toll Free: 1800932830

Please ask to be joined into the Trinity Biotech call.

A simultaneous webcast of the call can be accessed at:

<https://services.choruscall.com/mediaframe/webcast.html?webcastid=bJwDZEcn>

A replay of the call can be accessed until April 18, 2022 by dialling:

US Toll Free: 1-877-344-7529

International Toll: 1-412-317-0088

Replay Code: 5436077

To access the replay using an international dial-in number, please see the link below:

<https://services.choruscall.com/ccforms/replay.html>

A webcast of the call will be available for 30 days at:

<https://services.choruscall.com/mediaframe/webcast.html?webcastid=bJwDZEcn>

Replays will be available 1 hour after the end of the conference.

Use of Non-IFRS Financial Information

The Company reports financial results in accordance with IFRS. To supplement the consolidated financial statements presented in accordance with IFRS, the Company presents the Non-IFRS presentation of Adjusted EBITDA and Adjusted EBITDASO. These non-IFRS measures are not in accordance with, nor are they a substitute for, IFRS measures. The Company uses these Non-IFRS measures to evaluate and manage the Company's operations internally. The Company is also providing this information to assist investors in performing additional financial analysis. Reconciliation between the company's results on a IFRS and non-IFRS basis is provided in a table above.

The above mentioned numbers are unaudited.

Once-off charges are non-GAAP accounting presentations.

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 December 31, 2021 (unaudited)	Three Months Ended December 31, 2020 (unaudited)	Twelve Months Ended December 31, 2021 (unaudited)	Twelve Months Ended December 31, 2020 (unaudited)
Revenues	19,525	32,765	92,965	101,980
Cost of sales	(12,286)	(17,108)	(54,888)	(53,400)
Gross profit	7,239	15,657	38,077	48,580
Gross margin %	37.1%	47.8%	41.0%	47.6%
Other operating income	722	1,841	4,672	1,860
Research & development expenses	(941)	(1,284)	(4,497)	(5,080)
Selling, general and administrative expenses	(5,179)	(6,872)	(23,359)	(24,234)
Indirect share based payments	(154)	(276)	(1,096)	(780)
Operating profit	1,687	9,066	13,797	20,346
Financial income	-	-	3	36
Financial expenses	(1,201)	(1,224)	(4,811)	(4,892)
Net financing expense	(1,201)	(1,224)	(4,808)	(4,856)
Profit before tax , impairment, once-off & non-cash items	486	7,842	8,989	15,490
Income tax credit	1,186	730	166	182
Profit after tax before impairment, once-off & non-cash items	1,672	8,572	9,155	15,672
Non-cash financial income/(expense)*	(152)	(820)	572	(1,859)
Impairment & once-off items	(2,784)	(17,776)	(8,852)	(20,201)
(Loss)/Profit after tax	(1,264)	(10,024)	875	(6,388)
Earnings/(Loss) per ADS (US cents)	(6.0)	(48.0)	4.2	(30.6)
Diluted earnings/(loss) per ADS (US cents)**	(0.4)	(30.8)	16.1	(2.0)
Weighted average no. of ADSs used in computing basic earnings per ADS	20,901,703	20,901,703	20,901,703	20,901,703
Weighted average no. of ADSs used in computing diluted earnings per ADS	26,269,194	26,663,066	26,629,663	26,256,183

*Non-cash financial income/(expense) refers to accretion interest and fair value adjustments.

** Under IAS 33 Earnings per Share, diluted earnings per share cannot be anti-dilutive. In a reporting period where it is anti-dilutive, diluted earnings per ADS should be constrained to equal basic earnings per ADS.

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). Impairment, once-off charges & non-cash financial items are non-GAAP accounting presentations.

Trinity Biotech plc
Consolidated Balance Sheets

	December 31, 2021 US\$ '000 (unaudited)	September 30, 2021 US\$ '000 (unaudited)	June 30, 2021 US\$ '000 (unaudited)	December 31, 2020 US\$ '000 (unaudited)
ASSETS				
Non-current assets				
Property, plant and equipment	5,918	6,258	6,501	8,547
Goodwill and intangible assets	35,981	34,319	32,864	33,860
Deferred tax assets	4,101	3,711	3,617	4,185
Other assets	207	244	279	355
Total non-current assets	46,207	44,532	43,261	46,947
Current assets				
Inventories	29,123	32,116	34,705	30,219
Trade and other receivables	16,116	16,816	15,358	22,668
Income tax receivable	1,539	1,840	2,782	3,086
Cash, cash equivalents and deposits	25,910	27,475	28,618	27,327
Total current assets	72,688	78,247	81,463	83,300
TOTAL ASSETS	118,895	122,779	124,724	130,247
EQUITY AND LIABILITIES				
Equity attributable to the equity holders of the parent				
Share capital	1,213	1,213	1,213	1,213
Share premium	16,187	16,187	16,187	16,187
Treasury shares	(24,922)	(24,922)	(24,922)	(24,922)
Accumulated surplus	12,559	13,685	12,093	10,573
Translation reserve	(5,379)	(5,376)	(5,090)	(5,293)
Other reserves	23	23	23	23
Total equity/(deficit)	(319)	810	(496)	(2,219)
Current liabilities				
Income tax payable	22	1,018	751	154
Trade and other payables	17,107	18,324	21,304	26,488
Exchangeable senior note payable ¹	83,312	83,159	83,190	-
Provisions	50	376	376	416
Total current liabilities	100,491	102,877	105,621	27,058
Non-current liabilities				
Exchangeable senior note payable ¹	-	-	-	83,884
Other payables	13,865	14,555	15,283	16,619
Deferred tax liabilities	4,858	4,537	4,316	4,905
Total non-current liabilities	18,723	19,092	19,599	105,408
TOTAL LIABILITIES	119,214	121,969	125,220	132,466
TOTAL EQUITY AND LIABILITIES	118,895	122,779	124,724	130,247

¹ Exchangeable senior notes have a nominal value of US\$99.9 million with a maturity date on April 1, 2045, subject to earlier repurchase, redemption or exchange. The exchangeable notes (and the related embedded derivatives) have been presented within current liabilities since June 30, 2021 as the Company does not have an unconditional right to defer settlement of the exchangeable notes for at least 12 months after the reporting period due to the existence of a put option which allows the holders to put the exchangeable notes to the issuer at par on April 1, 2022. This accounting treatment of the exchangeable notes is required by IAS 1. On December 15, 2021, Trinity Biotech agreed terms with 5 holders of the exchangeable notes for the repurchase of approximately 99.7% of the outstanding notes. The agreement was conditional on certain lending conditions being met and required shareholder approval, which was obtained in January 2022. In respect of the company's financial position as at December 31, 2021, the agreement to repurchase the exchangeable notes is a non-adjusting event under IAS 10. For more information on the repurchase of the exchangeable

notes, refer to the Company's announcement on December 15, 2021 and January 27, 2022. Additional information relating to the accounting treatment for the exchangeable notes may be found in the most recently filed Company's Annual Report on Form 20-F filing filed with the U.S. Securities and Exchange Commission.

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 December 31, 2021 (unaudited)	Three Months Ended December 31, 2020 (unaudited)	Twelve Months Ended December 31, 2021 (unaudited)	Twelve Months Ended December 31, 2020 (unaudited)
Cash and cash equivalents at beginning of period	27,475	19,910	27,327	16,400
Operating cash flows before changes in working capital	5,733	4,678	16,484	18,179
Changes in working capital	(1,876)	10,164	(4,979)	7,688
Cash generated from operations	3,857	14,842	11,505	25,867
Net Interest and Income taxes (paid)/received	432	(1,142)	1,622	(886)
Capital Expenditure & Financing (net)	(2,356)	(3,615)	(8,691)	(10,435)
Payments for Leases (IFRS 16)	(720)	(670)	(2,841)	(3,031)
Free Cash Flow	1,213	9,415	1,595	11,515
Payment of HIV/2 License Fee	-		-	(1,112)
30-year Exchangeable Note interest payment	(1,998)	(1,998)	(3,996)	(3,996)
Refinancing Closing Fees	(780)	-	(780)	-
Proceeds received under Paycheck Protection Program	-	-	1,764	4,520
Cash and cash equivalents at end of period	25,910	27,327	25,910	27,327

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).