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Trinity Biotech Announces Results for Q2, 2021

DUBLIN, Ireland (September 9, 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 June 30, 2021.

Quarter 2 Results

Total revenues for Q2, 2021 were \$25.8m, which compares to \$16.0m in Q2, 2020, an increase of \$9.8m and which were broken down as follows:

	2020 Quarter 2	2021 Quarter 2	Increase
	US\$'000	US\$'000	%
Point-of-Care	1,267	1,958	54.5%
Clinical Laboratory	14,757	23,885	61.9%
Total	16,024	25,843	61.3%

Point-of-Care revenues for Q2, 2021 increased from \$1.3m to \$2.0m when compared to Q2, 2020, an increase of almost 55%. This increase was attributable to higher HIV revenues from Africa related sales. In Q2 2020, revenues were significantly impacted by logistical constraints caused by COVID-19. While these constraints have eased somewhat, COVID-19 continues to disrupt HIV testing in Africa and the associated purchase of Point-of-Care tests.

Clinical Laboratory revenues increased from \$14.8m to \$23.9m, which represents an increase of 61.9% compared to Q2, 2020. The increase is mainly due to strong revenues from 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. The Company noted a significant reduction in demand for new orders of VTM during early 2021 as COVID-19 testing volumes dropped and customers utilised stockpiled product. As such Q2 2021 VTM revenue primarily derived from closing out existing orders. While the situation relating to COVID-19 products remains very fluid, with the evolving impact of the Delta variant the Company has seen increased customer interest in VTM products over recent weeks and is taking steps to address any increase in demand that materialises.

In addition to increases in revenues from products within our COVID-19 portfolio of products, there was a significant increase in our Haemoglobins and Autoimmunity business in Q2 2021 compared to Q2 2020 as while COVID-19 public health restrictions remained in place, in many markets these restrictions were not as severe as in Q2 2020, thus allowing a partial return towards more normalised level of Haemoglobins and Autoimmunity testing.

Gross profit for Q2, 2021 amounted to \$11.0m, representing a gross margin of 42.7%. This is broadly similar to the 42.9% achieved in Q2, 2020.

Other operating income increased from \$2,000 in Q2 2020 to \$2.9m in Q2 2021. The \$2.9m income relates to loan funding received in 2020 under the U.S. government’s Paycheck Protection Program (“PPP”). Four PPP loans received by the Company in 2020, totalling \$2.9m, were forgiven during Q2 2021 and have therefore been recognised as income this quarter. These four loans were treated as short term liabilities at March 31, 2021.

Research and Development expenses decreased slightly to \$1.1m, whilst Selling, General and Administrative (SG&A) expenses increased by \$1.3m to \$6.3m when compared to Q2, 2020. SG&A expenses were unusually low in Q2 2020, due to the furloughing of employees as a result of the pandemic, government payroll supports related to COVID-19 which are not being claimed in 2021 and other cost savings. Q2 2021 SG&A costs include higher professional fees and sales team related costs compared to Q2 2020.

Operating profit for the quarter was \$6.3m, which represents an increase of \$5.8m compared to Q2, 2020 and was attributable to increased revenues and other operating income offset slightly by a lower gross margin and higher indirect costs.

Financial Expenses amounted to \$1.2m, which was in line with Q2, 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 (IFRS 16). Non-cash financial income of \$0.9m was recognised in this quarter’s income statement, again in relation to the Exchangeable Notes. This was due to a notional gain of \$1.0m arising due to a decrease in the fair value of the derivatives embedded in these notes as required by IFRS 9, partially offset by accretion interest on the Exchangeable Notes of \$0.1m.

The profit before tax, (before the impact of impairment, non-cash financial items and once-off charges) for the quarter was \$5.1m, in comparison to a loss of \$0.7m for the equivalent period last year.

The basic earnings per ADR (our equivalent to EPS) (excluding impairment, once-off charges and non-cash financial items) for the quarter was 21.2 U.S. cents versus a loss per ADR of 3.6 U.S. cents in Q2, 2020. Unconstrained diluted EPS (excluding impairment, once-off charges and non-cash financial items) for the quarter amounted to 20.3 U.S. cents, which compares to 1.0 U.S. cent in the equivalent quarter in 2020.

Earnings before interest, tax, depreciation, amortisation and share option expense (EBITDASO) for the quarter was \$7.4m, and was made up as follows:

	<i>\$m</i>
Operating Profit	6.3
Depreciation	0.6
Amortisation	0.2
Share Option Expense	0.3
<i>EBITDASO</i>	<i>7.4</i>

The above measures exclude the impact of impairment charges amounting to \$6.1m, more details of which are provided below.

Cash Flow

The Group's cash balance reduced by \$3.7m in Q2 2021. This cash reduction was driven by a \$2m interest payment on the Exchangeable Notes, working capital movements and capital expenditure.

For instance, trade & other payables reduced by c\$9.6m compared to Q1 2021. This reduction was mainly driven by the aforementioned forgiveness of the PPP loans, and a reduction in trade creditors & accruals as the Company paid VTM related suppliers for previously supplied raw materials while reducing the level of purchases of raw materials to reflect the reduced new orders for VTM products as the quarter continued.

Impairment

In accordance with the provisions of accounting standards under IFRS, a company is required to carry out periodic impairment reviews in order to determine the appropriate carrying value of its net assets. This period's review has resulted in a non-cash impairment charge of \$6.1m net of tax being recognised. A number of factors impacted this calculation including the Company's share price at 30 June 2021 which was lower than the share price at the time of the prior impairment review (31 December 2020), cash flow projections and net asset values across each of the Company's individual main business lines.

Business Developments

HIV Testing (TrinScreen™ HIV)

Trinity Biotech has been the main confirmatory test provider for the detection of the HIV virus on the African continent over many years. Trinity Biotech has developed a new product, TrinScreen™ HIV, specifically for the screening market, a market that is significantly larger than the confirmatory market. TrinScreen™ HIV has already undergone an independent evaluation sponsored by the World Health Organisation (WHO), yielding excellent results. The final part of the approval process includes WHO review of the multi-site clinical evaluation which concluded in Africa in 2020. This final part of the submission dossier was submitted to the WHO in March 2021.

In June 2021, the Company received an update from the WHO on the approval process. The WHO confirmed that their screening of the submission dossier was complete and the dossier was to move forward to the final assessment phase.

In September 2021 the Company received a further update from the WHO on the approval process. The WHO confirmed that the final assessment phase is now well advanced. This is yet another important milestone in the approval process for TrinScreen™ HIV. This product, once approved, will allow the Company to build on its strong brand presence in HIV testing in Africa. The Company believes the TrinScreen™ HIV product has a number of key advantages compared to the current main incumbent product and expects a positive response from the WHO and the opportunity to expand its market share in the African HIV market.

The Company is preparing for the automated manufacture of TrinScreen™ HIV at its facility in Ireland in anticipation of WHO approval.

COVID-19 Rapid Antigen Test

In Q1 2021, the Company began a R&D process transformation programme. The objectives of this programme are to deliver new high quality products to the market faster and at a lower cost of production so as to allow the Company capture a greater market share and deliver higher

profitability. To deliver on these objectives, the transformation programme has focused on optimising the core R&D processes and integrating these with manufacturing readiness and the regulatory approval process.

Our COVID-19 rapid antigen test is the first product development project to be brought through this revised R&D process. As a result of an expectation of higher demand due to the impact of the Delta variant, the Company has also decided to increase the priority of this test and is committing additional internal resources to the development of this test in the short term. The streamlined R&D process, coupled with targeted additional internal resource allocation has significantly reduced our expected time to market. As such, we now expect that we will have achieved CE mark during Q2 2022 which will allow us to launch the product in Europe. While we do expect to launch the product in the US, the regulatory path for such products remains fluid and thus the Company will continue to assess what may be the most appropriate regulatory approval pathway to allow a US launch of the product.

The COVID-19 rapid antigen test can be run without any specialised equipment, provides a result in 12 minutes and utilises an easy-to-use anterior nasal swab sample. The test design has demonstrated excellent analytical results, and the focus for the remainder of the development process will be on transfer to automated manufacture and clinical validation. The COVID-19 rapid antigen test is built on the same core lateral flow technology as our TrinScreen HIV test and thus the Company has significant automated manufacturing capacity to produce the test.

The core lateral flow technology is customisable for many test types, and we expect to continue to expand our test offering with this test platform and leverage the cost benefits of common manufacturing processes. We intend to further expand the test menu in Infectious Disease in 2022 with a focus on high volume markets to capitalise on the synergies of our Sales, Marketing and Distribution capabilities and existing relationships with NGO's.

Comments

Commenting on the results John Gillard, Chief Financial Officer stated, "The Company delivered another strong quarter in Q2 2021 with gross profit of \$11m compared to \$6.9m in Q2 2020. This translated into an operating profit (before impairments) for Q2 2021 of \$6.3m compared to \$0.5m in Q2 2020."

Ronan O'Caoimh, Chief Executive Officer stated, "We are pleased to have another strong quarter with a 61% increase in revenue compared to Q2 2020, primarily driven by strong revenues from within our COVID-19 related portfolio of products and a partial rebound in our core revenues.

In addition, we have made significant progress in streamlining our R&D processes with the aim of bringing new high quality products to market faster and at a lower cost of production so as to allow the Company capture a greater market share and deliver higher profitability, particularly in our lateral flow business. We are excited that these changes should allow us expand our range of lateral flow tests more quickly and efficiently. For instance, this revised process is allowing us bring forward the expected CE mark and European launch of our COVID-19 rapid antigen test to Q2 2022, which is several quarters earlier than our initial development plan. The test can be run without any specialised equipment, provides a result in 12 minutes and utilises an easy-to-use anterior nasal swab sample.

Given the evidence of breakthrough infections for those vaccinated and the continuing threat of new variants, we now expect rapid antigen testing to have a continuing place in the overall public health response to COVID-19, even as vaccinations continue and that this may be a significant market for

Trinity Biotech into the future. As such we have prioritised the allocation of internal resources with the intent of bringing this test to market earlier than initially planned.”

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 June 30, 2021 (unaudited)	Three Months Ended June 30, 2020 (unaudited)	Six Months Ended June 30, 2021 (unaudited)	Six Months Ended June 30, 2020 (unaudited)
Revenues	25,843	16,024	51,437	37,201
Cost of sales	(14,816)	(9,153)	(29,497)	(21,053)
Gross profit	11,027	6,871	21,940	16,148
Gross margin %	42.7%	42.9%	42.7%	43.4%
Other operating income	2,906	2	2,907	16
Research & development expenses	(1,056)	(1,153)	(2,493)	(2,531)
Selling, general and administrative expenses	(6,280)	(5,006)	(12,300)	(11,091)
Indirect share based payments	(311)	(213)	(690)	(348)
Operating profit	6,286	501	9,364	2,194
Financial income	1	2	2	34
Financial expenses	(1,202)	(1,221)	(2,412)	(2,453)
Net financing expense	(1,201)	(1,219)	(2,410)	(2,419)
Profit/(Loss) before tax , impairment, once-off & non-cash items	5,085	(718)	6,954	(225)
Income tax expense	(655)	(32)	(760)	(162)
Profit/(Loss) after tax before impairment, once-off & non-cash items	4,430	(750)	6,194	(387)
Non-cash financial income/(expense)*	855	(717)	693	(877)
Impairment & once-off items	(6,068)	-	(6,068)	(2,425)
Profit/(Loss) after tax	(783)	(1,467)	819	(3,689)
Earnings/(Loss) per ADR (US cents)	(3.7)	(7.0)	3.9	(17.6)
Earnings/(Loss) per ADR (US cents)***	21.2	(3.6)	29.6	(1.9)
Diluted earnings per ADR (US cents)**	20.3	1.0	30.3	6.3
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	26,728,320	25,931,574	27,008,193	25,745,569

*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 ADR should be constrained to equal basic earnings per ADR. Diluted EPS is calculated excluding impairment, once-off charges & non-cash financial items.

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

Trinity Biotech plc
Consolidated Balance Sheets

	June 30, 2021 US\$ '001 (unaudited)	Mar 31, 2021 US\$ '000 (unaudited)	Dec 31, 2020 US\$ '000 (unaudited)
ASSETS			
Non-current assets			
Property, plant and equipment	6,501	8,648	8,547
Goodwill and intangible assets	32,864	35,200	33,860
Deferred tax assets	3,617	4,205	4,185
Other assets	279	315	355
Total non-current assets	43,261	48,368	46,947
Current assets			
Inventories	34,705	37,582	30,219
Trade and other receivables	15,358	14,864	22,668
Income tax receivable	2,782	2,888	3,086
Cash, cash equivalents and deposits	28,618	32,277	27,327
Total current assets	81,463	87,611	83,300
TOTAL ASSETS	124,724	135,979	130,247
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the parent			
Share capital	1,213	1,213	1,213
Share premium	16,187	16,187	16,187
Treasury shares	(24,922)	(24,922)	(24,922)
Accumulated surplus	12,093	12,561	10,573
Translation reserve	(5,090)	(5,189)	(5,293)
Other reserves	23	23	23
Total deficit	(496)	(127)	(2,219)
Current liabilities			
Income tax payable	751	389	154
Trade and other payables	21,304	30,881	26,488
Exchangeable senior note payable ¹	83,190	-	-
Provisions	376	376	416
Total current liabilities	105,621	31,646	27,058
Non-current liabilities			
Exchangeable senior note payable ¹	-	84,045	83,884
Other payables	15,283	15,625	16,619
Deferred tax liabilities	4,316	4,790	4,905
Total non-current liabilities	19,599	104,460	105,408
TOTAL LIABILITIES	125,220	136,106	132,466
TOTAL EQUITY AND LIABILITIES	124,724	135,979	130,247

¹ Exchangeable senior notes having a nominal value of US\$99.9 million mature on April 1, 2025, subject to earlier repurchase, redemption or exchange. The exchangeable notes (and the related embedded derivatives) have been presented within current liabilities at 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. Additional information relating to the accounting treatment for the

exchangeable notes may be found in the 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

<i>(US\$000's)</i>	Three Months Ended June 30, 2021 (unaudited)	Three Months Ended June 30, 2020 (unaudited)	Six Months Ended June 30, 2021 (unaudited)	Six Months Ended June 30, 2020 (unaudited)
Cash and cash equivalents at beginning of period	32,277	13,244	27,327	16,400
Operating cash flows before changes in working capital	4,460	1,311	8,524	3,779
Changes in working capital	(3,155)	1,471	(1,326)	74
Cash generated from operations	1,305	2,782	7,198	3,853
Net Interest and Income taxes (paid)/received	(92)	(34)	98	397
Capital Expenditure & Financing (net)	(2,154)	(2,163)	(4,350)	(4,919)
Payments for Leases (IFRS 16)	(720)	(781)	(1,421)	(1,571)
Free cash flow	(1,661)	(196)	1,525	(2,240)
Payment of HIV/2 License Fee	-	-	-	(1,112)
30 year Exchangeable Note interest payment	(1,998)	(1,998)	(1,998)	(1,998)
Proceeds received under Paycheck Protection Program	-	4,520	1,764	4,520
Cash and cash equivalents at end of period	28,618	15,570	28,618	15,570

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