Trinity Biotech Announces Quarter 2 2022 Financial Results And Preliminary Q3 2022 Revenue Guidance

DUBLIN, Ireland, Nov. 03, 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 the Company's results for the quarter ended June 30, 2022 and preliminary guidance with respect to Q3 revenues.

Summary Highlights:

- Total revenues for Q2 2022 were $18.5m.
- Excluding our Covid focused PCR Viral Transport Media ("VTM") products, Q2 2022 revenues of $18.0m were broadly flat compared to Q2 2021 and were up 7% compared to Q1 2022. A strong YoY increase in revenues in our diabetes A1c product line revenues of over 25% offset a decline in legacy infectious disease product demand in Asia due to continuing COVID-19 lockdowns.
- Preliminary estimates for Q3 2022 indicate expected revenues of between $19m to $20m. Q3 Global Health HIV orders for Africa, which are often difficult to predict, increased compared to Q2 2022 and we expect our HIV point of care ("PoC") revenue to grow over 30% on a QoQ basis. Fitzgerald continues to perform well with a 25% QoQ revenue growth profile expected.
- In May 2022, the Company announced the closing of a $45.2m investment from MiCo Ltd ("MiCo"). The investment consists of an equity investment of $25.2m acquired for $2.25 per ADS and a seven-year, unsecured junior convertible note of $20.0m with an interest rate of 1.5% and mandatory conversion price of $3.24.
- As part of its ongoing balance sheet restructuring, the Company made a partial early repayment of its term loan with the Perceptive group in May 2022. To date, this partial repayment has saved the Company cash interest expense of $2.3m.
- In late August 2022 the Company submitted its 510k submission to the FDA seeking US regulatory approval of its Premier Resolution Haemoglobin Variants instrument. Subject to FDA approval, commercial sales are expected to begin by Q2 2023.
- The Company is finalising the development of a lower cost, mid throughput A1c instrument that leverages the core consumables technology from our existing Premier 9210 instrument, targeting developing markets. We are also working on the launch of a clinical laboratory reader/processor range to complement our autoimmune products for a 2023 launch.
- Since World Health Organisation approval in February 2022 of our TrinScreen HIV product, the relevant Kenyan Ministry of Health task force recommended TrinScreen as the first line screening test for Kenya's new HIV testing algorithm.
- Platform optimisation actions to date have resulted in a more efficient workforce. Our average headcount in the six months ended June 30, 2022 was approximately 410

compared to over 500 in the six months ended June 30, 2021 and we expect total headcount to be under 400 by the end of 2022. Trinity Biotech continues to focus on improving gross margin, earnings, and cash contribution from existing operations through focusing on operational efficiency.

- The Company is undertaking a portfolio wide capital and talent allocation review emphasising maximizing return on capital and cash contribution.
- Supply chain and commercial actions are underway to significantly optimise margins in our haemoglobins operation, including insourcing key elements of our consumable column manufacturing. We are also expanding manufacturing capacity at our Jamestown facility to address demand growth for our autoimmune products while also offsetting excess production capacity from the expected run off in demand for our legacy infectious disease products.
- We have launched a strategic review of expansion opportunities in the Point of Care and decentralised testing markets to take advantage of rapidly evolving patient expectations and technology, new non-traditional market entrants and payor focus on controlling healthcare costs. We are actively exploring acquisition and partnership strategies in these areas aimed at accessing channel distribution, product innovation and user experience expertise and intend to make a substantial investment toward this effort over the next 18 months in our Buffalo, NY lab which is well positioned to serve the decentralised testing market because, unlike many other US labs, it is certified to process samples from all 50 US states.
- The Company continues to focus on attracting and incentivising a world class leadership team with the recent appointment of Aris Kekedjian as CEO and Chairman, and by making further experienced hires to drive excellence in supply chain, regulatory compliance, business intelligence, corporate development and technology.
- Trinity Biotech will be a presenter at the 2022 Piper Sandler Healthcare Conference on Thursday, December 1, 2022. Aris Kekedjian, Chairman and Chief Executive Officer, and John Gillard, Chief Financial Officer, will represent the Company and will also host a number of 1-on-1 meetings with investors.

Details

Quarter 2 Unaudited Results

Total revenues for Q2, 2022 were $18.5m which compares to $25.8m in Q2, 2021, a decrease of 28.6% and which were broken down as follows:

	2021 Quarter 2 US$'000	**2022 Quarter 2 US$'000**	**(Decrease) %**
Clinical Laboratory	23,885	16,624	(30.4%)
Point-of-Care	1,958	1,840	(6.0%)
Total	**25,843**	**18,464**	**(28.6%)**

Clinical Laboratory revenues were $16.6m, compared to $23.9m in Q2, 2021, representing a decrease of $7.3m or 30.4%. This decrease is mainly due to a reduction of approximately $7.4m in revenues from our PCR VTM products compared to Q2 2021. Sales volumes for PCR VTM products have decreased since the first half of 2021 due to a significant scaling down of PCR testing programs for Covid-19. In addition, there was an approximately $800k reduction in revenues in our legacy infectious disease product range compared to Q2 2021 as continuing COVID-19 lockdowns in Asia hampered demand for these products.

Our diabetes A1c revenues continue to grow with a $1.2m or 27% increase in revenues compared to Q2 2021 and we expect earnings from our A1c testing business to increase in the near term given our increasing instrument installed base and operational & strategic supply chain changes we began executing in Q3 2022 to reduce the cost of goods of our tests.

PoC revenues for Q2, 2022 decreased from $2.0m to $1.8m when compared to Q2, 2021, a decrease of 6.0%. This was mainly attributable to lower sales of HIV tests in Africa. Such fluctuations are a feature of the African HIV market which exhibits irregular ordering patterns from customers.

Gross profit for Q2, 2022 decreased from $11.0m to $6.5m when compared to Q2, 2021. The gross margin of 35.3% for Q2, 2022 was 7.4% lower the margin achieved in Q2, 2021, with the reduction largely due to sales mix changes, the reduction in higher margin PCR VTM and inflationary increases in the price of raw materials.

Research and development expenses declined from $1.1m to $1.0m when compared to Q2, 2021 due to a continued focus on cost control measures. Selling, general and administrative (SG&A) expenses were $6.5m in Q2, 2022, a reduction of $0.1m compared to Q2, 2021. The strengthening of the US Dollar against the Euro in Q2, 2022 has contributed to a reduction in our Euro-denominated SG&A expenses and this was partly offset by transaction related management bonuses and higher travel costs.

An impairment charge of $0.5m was recorded in Q2, 2022, compared to an impairment charge of $6.1m in Q2, 2021. 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 $0.5m being recognised. A number of factors impacted this calculation including the Company’s share price on June 30, 2022, which was lower than the share price at the time of the prior impairment review (31 December 2021), cash flow projections and net asset values across each of the Company’s individual main business units.

Operating loss for the quarter was $1.4m, which represents a decrease in profitability of $1.6m compared to Q2, 2021 and was attributable to a lower gross profit, partly offset by

lower indirect costs and a lower impairment charge.

Financial income for Q2, 2022 was zero compared to $1.0m for Q2, 2021, which was due to a fair value adjustment of the derivatives embedded in the exchangeable notes. There is no equivalent financial income in Q2 2022 because 99.7% of the exchangeable notes were retired in January 2022.

Financial expenses in Q2, 2022 were $8.3m compared to $1.4m in Q2, 2021, an increase of $6.9m. A breakdown of the financial expenses is shown in the table below:

US$m	**Q2 2022**	**Q2 2021**
Penalty for early partial settlement of term loan	3.5	–
Term loan accretion interest	2.1	–
Term loan cash interest	1.9	–
Fair value movement for derivative balances related to term loan	0.4	–
Accretion interest on IFRS 16 leases	0.2	0.2
Convertible Note interest	0.2	–
Exchangeable Notes interest	0.0	1.2
Total financial expense	**8.3**	**1.4**

In May 2022 the Company made an early partial settlement of the senior secured term loan of $34.5m and in accordance with the term loan's credit agreement, there was a penalty for early repayment of $3.5m. To date, the Company has benefitted from a cash saving of approximately $2.3m by repaying a portion of the term loan early. The minimum liquidity covenant for the term loan was amended after the early repayment, so that the unrestricted cash balance that the Company is required to maintain was reduced from $5.0m to $2.0m until May 2023.

In Q2, 2022, accretion interest of $2.1m was recorded for the senior secured term loan. The accretion interest is higher in Q2 2022 than the expected run rate because of the early partial settlement of the term loan which resulted in an acceleration of the accretion interest expense under the applicable IFRS accounting provisions.

The loss after tax for continuing operations for the quarter was $9.7m in comparison to a loss of $0.8m for the equivalent period last year. This decrease in profitability of $8.9m was primarily due to lower gross profit, lower other operating income and higher financial expenses this quarter, with the partial early term loan repayment the main driver for the increase in financial expenses.

Loss before interest, tax, depreciation, amortisation and share option expense for the year and excluding impairment charges for Q2 2022 (Adjusted EBITDASO) was $0.5m. This is made up as follows:

	$m
Operating loss	(1.4)
Impairment charge	0.5
Depreciation	0.1
Amortisation	0.2
Adjusted EBITDA	***(0.6)***
Share option expense	0.1
Adjusted EBITDASO	***(0.5)***

The basic loss per ADS for Q2, 2022 was 28.6 cents versus 3.7 cents in Q2, 2021. For both Q2, 2022 and Q2, 2021, the diluted loss per ADS was the same as the basic loss per ADS as potential issuances of ordinary shares were anti-dilutive as their conversion to ADSs would not increase the loss per ADS.

Use of Non-IFRS Financial Measures

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. 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.

Investment by MiCo Group

In May 2022, the Company announced the successful closure of a $45.2m investment from MiCo Ltd ("MiCo"). MiCo, a KOSDAQ-listed and Korea-based company, is engaged in the biomedical business through its affiliate MiCo BioMed. The investment consists of an equity investment of $25.2m and a seven-year, unsecured junior convertible note of $20.0m. The convertible note has an interest rate of 1.5%. The convertible note mandatorily converts into ADSs if the volume weighted average price of the Company's ADSs is at or above $3.24 for any five consecutive NASDAQ trading days.

The convertible loan is accounted for as a compound financial instrument containing both an equity and liability element. The debt component is accounted for at amortised cost in accordance with IFRS 9. At June 30, 2022, the carrying value of the convertible note's debt component was $13.4m and accretion interest of $120,000 was recognised as a financial expense in the six-months ended June 30, 2022. The equity component of the convertible note is $6.7m and is recorded in the equity section of the Balance Sheet. There is no remeasurement of the equity element following initial recognition.

Liquidity

The Group's cash balance increased from $10.1m to $10.5m in Q2, 2022, an increase of $0.4m. An investment of $45.2m from the Mico Group was received during the quarter and this was primarily used to fund the $34.5m early repayment of the term loan and a related penalty for the early repayment of $3.5m.

Cash used by operations during Q2, 2022 was $1.9m. During Q2, 2022 the Company had capital expenditure cash outflows of $1.8m and payments for property leases of $0.7m. Interest payments in the quarter were $2.0m.

Q3 2022 Revenue Guidance

Preliminary estimates of revenues for Q3 2022 indicate that revenues are expected to be within the range of approximately $19m to $20m with the expected increase in revenue primarily driven by an expected increase of over 30% in HIV PoC revenue and an approximate 25% increase in revenue in our Life Sciences supply business, Fitzgerald Industries.

TrinScreen HIV Update

- Since Trinity Biotech received World Health Organisation approval in February 2022 for our new HIV screening product, TrinScreen HIV, we have submitted the product for inclusion on the HIV screening programme of the national HIV rapid algorithm in Kenya. In addition, the pre-submission process has been started in several other African countries.
- Trinity Biotech chose Kenya as the first country to submit TrinScreen HIV for inclusion in the national HIV algorithm given its large market size, estimated at 5 to 6 million tests per year, and its prestigious and leadership role as an innovator in HIV management in Africa.
- In Kenya, a technical taskforce appointed by the Ministry of Health to undertake a review of Kenya's HIV testing algorithm recommended TrinScreen HIV as the first line HIV screening test for Kenya's new HIV testing algorithm 2022.
- That Kenya has recommended TrinScreen HIV as the HIV screening test is a significant vote of confidence in TrinScreen HIV and our Africa Team.
- The use of the new HIV algorithm has been delayed due to (1) the change of government in Kenya following the election in August 2022 and (2) legal objections by competitors regarding the overall HIV algorithm evaluation process.
- The new government is now in place and we understand they are motivated to scale up the HIV rapid testing programme to pre-COVID-19 levels.
- We understand the implementation of the new HIV testing algorithm will begin before the end of the year and expect the first order to arrive shortly.
- Target countries for TrinScreen HIV for active evaluation in 2023 have a combined estimated market size of 30 million tests annually.

Premier Resolution FDA 510k Submission

- In late August 2022, the Company submitted its 510k submission to the FDA for US regulatory approval of its Premier Resolution Haemoglobin Variants instrument.
- This product has already been launched in Europe under the CE mark but requires FDA approval in order to be sold in the US and certain other key markets globally.
- The Company expects to receive 510k approval for the Premier Resolution by Q2 2023 and this should drive further revenue and earnings growth in our Haemoglobins business.

Comments

Commenting, Aris Kekedjian, Chief Executive Officer and Chairman stated "I'm delighted to lead Trinity Biotech at such an exciting time of change and transformation with the shift to decentralised diagnostics. The company has many of the capabilities, and the experience, to become a key platform in this evolving ecosystem. In addition, our prospects in the autoimmune segment are particularly enticing and likely an area of further investment. We continue to enhance our team and streamline our operations to drive agility and efficiency to maximise shareholder value. I look forward to engaging with shareholders in the coming weeks to lay out our strategy for growth and profitability."

Commenting, John Gillard, Chief Financial Officer stated "The Company made further substantial progress in strengthening its balance sheet and reducing the cash cost of its debt during Q2 2022. Given the hardening of debt markets over the course of 2022 this action has been shown to be timely and beneficial. The Company continues to invest in future growth, especially with the submission for FDA approval for our Premier Resolution and progress in the adoption of our WHO approved TrinScreen HIV product in Africa."

Forward-Looking Statements

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.

About Trinity Biotech

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, 2022 (unaudited)**	**Three Months Ended June 30, 2021 (unaudited)**	**Six Months Ended June 30, 2022 (unaudited)**	**Six Months Ended June 30, 2021 (unaudited)**
Revenues	**18,464**	**25,843**	**37,240**	**51,437**
Cost of sales	(11,937)	(14,816)	(23,443)	(29,497)
Gross profit	**6,527**	**11,027**	**13,797**	**21,940**
Gross margin %	*35.3%*	*42.7%*	*37.0%*	*42.7%*
Other operating income	1	2,906	1	2,907
Research & development expenses	(984)	(1,056)	(1,949)	(2,493)
Selling, general and administrative expenses	(6,459)	(6,591)	(13,190)	(12,990)
Impairment charges	(519)	(6,068)	(519)	(6,068)
Operating (Loss)/Profit	**(1,434)**	**218**	**(1,860)**	**3,296**
Financial income	0	1,018	0	1,019
Financial expenses	(8,300)	(1,364)	(20,303)	(2,736)
Net financing expense	(8,300)	(346)	(20,303)	(1,717)
(Loss)/Profit before tax	**(9,734)**	**(128)**	**(22,163)**	**1,579**
Income tax credit/(expense)	29	(655)	180	(760)
Profit/(Loss) for the period on continuing operations	**(9,705)**	**(783)**	**(21,983)**	**819**
Profit/(Loss) for the period on discontinued operations	(1)	**–**	(2)	**–**
Profit/(Loss) for the period (all attributable to owners of the parent)	**(9,706)**	**(783)**	**(21,985)**	**819**
(Loss)/ Earnings per ADS (US cents)	(28.6)	(3.7)	(75.1)	3.9
Diluted (loss)/ earnings per ADS (US cents)	(28.6)	(3.7)	(75.1)	3.9

Weighted average no. of ADSs used in computing basic and diluted earnings per ADS	33,952,095	20,901,703	29,289,617	20,901,703

Trinity Biotech plc

Consolidated Balance Sheets

	June 30, 2022 US$ '000 (unaudited)	March 31, 2022 US$ '000 (unaudited)	December 31, 2021 US$ '000
ASSETS			
Non-current assets			
Property, plant and equipment	6,261	5,634	5,918
Goodwill and intangible assets	38,743	37,320	35,981
Deferred tax assets	4,553	4,478	4,101
Derivative financial asset	140	219	–
Other assets	207	175	207
Total non-current assets	49,904	47,826	46,207
Current assets			
Inventories	29,109	29,627	29,123
Trade and other receivables	15,913	16,898	16,116
Income tax receivable	1,762	1,734	1,539
Cash, cash equivalents and deposits	10,453	10,012	25,910
Total current assets	57,237	58,271	72,688
TOTAL ASSETS	107,141	106,097	118,895
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the parent			
Share capital	1,963	1,445	1,213
Share premium	53,297	21,874	16,187
Treasury shares	(24,922)	(24,922)	(24,922)
Accumulated surplus/(deficit)	(9,103)	481	12,559
Translation reserve	(5,439)	(5,186)	(5,379)
Other reserves	23	23	23
Total equity/(deficit)	15,819	(6,285)	(319)
Current liabilities			
Income tax payable	21	40	22
Trade and other payables	13,600	15,637	17,107
Exchangeable senior note payable	210	210	83,312
Provisions	50	50	50
Total current liabilities	13,881	15,937	100,491
Non-current liabilities			
Senior secured term loan	43,990	76,246	–
Derivative financial liability	2,002	1,671	–

Convertible Note	13,372	–	–
Other payables	12,723	13,279	13,865
Deferred tax liabilities	5,354	5,249	4,858
Total non-current liabilities	77,441	96,445	18,723
TOTAL LIABILITIES	91,322	112,382	119,214
TOTAL EQUITY AND LIABILITIES	107,141	106,097	118,895

Trinity Biotech plc
Consolidated Statement of Cash Flows

	Three Months Ended June 30, 2022 (unaudited)	Three Months Ended June 30, 2021 (unaudited)	Six Months Ended June 30, 2022 (unaudited)	Six Months Ended June 30, 2021 (unaudited)
Cash flows from operating activities				
Profit/(loss) for the period	(9,706)	(783)	(21,985)	819
Adjustments to reconcile net profit/(loss) to cash provided by operating activities:				
Depreciation	47	577	479	1,136
Amortisation	214	240	442	458
Income tax (credit)/expense	(29)	655	(180)	760
Financial income	–	(1,018)	–	(1,019)
Financial expense	8,300	1,364	20,303	2,736
Share-based payments	122	312	319	693
Foreign exchange gains on operating cash flows	(191)	(276)	(149)	(67)
Impairment charge	519	6,068	519	6,068
Other non-cash items	995	(2,774)	305	(3,144)
Net movement on working capital	(2,217)	(3,155)	(3,481)	(1,326)
Cash (used)/generated from operations	**(1,946)**	**1,210**	**(3,428)**	**7,114**
Interest paid	(1)	(21)	(3)	(25)
Interest received	2	1	2	2
Income taxes received/(paid)	13	(72)	1	120
Net cash (used)/generated by operating activities	**(1,932)**	**1,118**	**(3,428)**	**7,211**
Cash flows from investing activities				
Payments to acquire intangible assets	(1,658)	(1,742)	(3,211)	(3,288)
Acquisition of property, plant and equipment	(143)	(389)	(305)	(969)
Net cash used in investing activities	**(1,801)**	**(2,131)**	**(3,516)**	**(4,257)**
Cash flows from financing activities				
Issue of ordinary share capital including share premium (net of issuance costs)	25,019	–	25,019	–
Net proceeds from new senior secured term loan	–	–	80,014	–

Proceeds for convertible note issued	20,000	–	20,000	
Expenses paid in connection with debt financing	(40)	–	(2,356)	–
Repayment of senior secured term loan	(34,500)	–	(34,500)	–
Penalty for early settlement of term loan	(3,450)	–	(3,450)	–
Purchase of exchangeable notes	–	–	(86,730)	–
Interest paid on senior secured term loan	(1,920)	–	(3,706)	–
Interest paid on convertible note	(49)	–	(49)	–
Proceeds from Paycheck Protection loans	–	–	–	1,764
Interest payment on exchangeable notes	(4)	(1,998)	(1,289)	(1,998)
Payment of lease liabilities	(729)	(743)	(1,500)	(1,472)
Net cash generated/(used) in financing activities	**4,327**	**(2,741)**	**(8,547)**	**(1,706)**
Increase/(decrease) in cash and cash equivalents and short-term investments	594	(3,754)	(15,491)	1,248
Effects of exchange rate movements on cash held	(153)	95	34	43
Cash and cash equivalents and short-term investments at beginning of period	10,012	32,277	25,910	27,327
Cash and cash equivalents and short-term investments at end of period	**10,453**	**28,618**	**10,453**	**28,618**

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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