Trinity Biotech Announces Q3 2022 Financial Results

DUBLIN, Ireland, Dec. 15, 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 September 30, 2022.

Summary Highlights:

- Total revenues for Q3 2022 were $19.5m. Excluding our Covid focused PCR Viral Transport Media ("VTM") products, Q3 2022 revenues of $19.2m were marginally higher by 2% compared to Q3 2021 and were up 6% compared to Q2 2022.
- A strong YoY 30% increase in revenues attributable to both our Haemoglobins and Fitzgerald Industries Life Sciences businesses offset the timing impact of atypically concentrated sales of UniGold HIV in Q3 2021. In addition, pricing changes and capacity optimisation actions in our Autoimmune product business led to a 30%+ increase compared to the same period in 2021.
- Quarter over quarter revenue momentum was driven by Fitzgerald Industries at 25%, reflecting actions to optimize demand generation throughout the year, strong demand for UniGold HIV with an increase of over 35% and over 20% Autoimmune product growth
- We are experiencing particularly strong demand for our Haemoglobins products in AsiaPac and Latin America, with well over 50% YoY revenue growth in AsiaPac and over 40% YoY revenue growth in Latin America. We continue to scale our commercial coverage in these markets where the increase in diabetes and propensity for haemoglobin variants is at some of its highest rates and our boronate affinity technology has a particular competitive advantage.
- In late August 2022 the Company submitted its 510k submission to the FDA seeking US regulatory approval of its Premier Resolution Haemoglobin Variants instrument and expects to launch the product in the US in Q2 2023.
- In November 2022, the Company initiated the development of its next generation flagship diabetes HbA1c instrument, the Premier 9210. Expected to launch in Q3 2023, it is planned to feature an improved, backward compatible reagent column system that will feature up to 3x the injection capacity and stability, limited calibration, improved user interface and lab system integration. In addition, this system should underpin the lower cost, mid throughput A1c instrument currently in development.
- Since World Health Organisation approval in February 2022 of our TrinScreen HIV product, the Kenyan Ministry of Health task force recommended it as the first line screening test for Kenya's new HIV testing algorithm. We expect to conclude the current pilot program in Kenya by year-end, deliver initial Ministry of Health orders in Q1 2023 and ramp up to approximately 6 million tests per year.
- The Company is in partnership negotiations with a number of rapid test innovators to

leverage its lateral flow biological development and manufacturing capabilities and provide access to its global distribution channels. In addition to capital efficient growth, this strategy provides early access to intellectual property associated with evolving user interface concepts.

- Improved design for manufacturing, supply chain enhancements and insourcing actions are underway seeking to significantly optimise margins across the portfolio. In Q3, 2022 we focused on streamlining the portfolio with the elimination of loss-making legacy products and inventory. We continue to consolidate multi-product flexible production in our Jamestown facility with the transfer of immunofluorescence and urine tube manufacturing from Buffalo, NY and Burlington, Canada respectively.
- The Company continues to focus on attracting and developing a world class leadership team with the recent appointments of a Chief Technology Officer, Head of Quality and Regulatory Affairs and Global Supply Chain Leader.
- Trinity Biotech was recently featured at the 2022 Piper Sandler Healthcare Conference, where Aris Kekedjian, Chairman and Chief Executive Officer, outlined the Company's strategic growth playbook. A copy of the presentation is available at www.trinitybiotech.com.

Third Quarter Results (Unaudited)

Total revenues for Q3, 2022 were $19.5m which compares to $22.0m in Q3, 2021, a decrease of 11.4% and which were broken down as follows:

	2021 Quarter 3 US$'000	**2022 Quarter 3 US$'000**	**(Decrease) %**
Clinical Laboratory	17,891	16,966	(5.2%)
Point-of-Care	4,113	2,536	(38.3%)
Total	**22,004**	**19,502**	**(11.4%)**

Clinical Laboratory revenues were $17.0m, compared to $17.9m in Q3, 2021, representing a decrease of $0.9m or 5.2%. This decrease is due to a reduction of approximately $2.9m in revenues from our PCR VTM products compared to Q3, 2021. Sales volumes for PCR VTM products have decreased since 2021 due to a significant scaling down of PCR testing programs for Covid-19.

Excluding VTM products, Clinical Laboratory revenues increased by almost $2.0m or 13.4% to $16.6m compared to $14.6m in Q3, 2021.

The underlying growth in Clinical Laboratory revenues was driven by strong performances from our haemoglobins and Fitzgerald Industries businesses. Haemoglobins revenues continue to grow, with a $1.4m or 30.3% increase in revenues this quarter compared to Q3, 2021. We expect revenues from this business to continue this growth trend driven by a

higher instrument installed base and operational and strategic supply chain changes, which we expect will drive margin increase.

Fitzgerald Industries, which is the Group's distributor of raw materials for the life sciences industry, recorded a revenue increase of $0.9m or 30.2% compared to Q3, 2021 and an increase of 24.6% compared to Q2, 2022.

Lastly, there was a reduction of $0.3m in Clinical Laboratory revenues for our legacy infectious disease range of products compared to Q3, 2021 as continuing COVID-19 lockdowns in Asia hampered demand for these products.

Point-of-Care revenues for Q3, 2022 decreased from $4.1m to $2.5m when compared to Q3, 2021, a decrease of 38.3%. Q3, 2021 marked the highest individual quarter for Point-of-Care revenues in the last three fiscal years and was driven by an unusually high volume of HIV tests sold in Africa. The $2.5m of Point-of-Care revenues recorded for Q3, 2022 represents an increase of 38% compared to Q2, 2022.

	Q3 2022 US$000
Revenues	19,502
Cost of sales (including significant excess and obsolescence charges related to inventory of $4,697)	17,487
Gross profit	2,015
Gross margin %	10.3%
Adjusted Gross profit (excluding significant excess and obsolescence charges related to inventory of $4,697)	6,712
Adjusted Gross margin %	34.4%

In Q3, 2022, gross profit was $2.0m, equating to a gross margin of 10.3%. This gross profit reflects significant excess inventory and obsolescence charges of $4.7m, consisting of the following:

1. VTM inventory write down ($3.5m) – as previously disclosed, the situation relating to COVID-19 products was fluid and as such we chose to retain the capability to flex manufacturing volumes should market conditions warrant. As such, we maintained a significant inventory of critical raw materials to allow a ramping up of COVID focused VTM production to meet peak demand as it was important that we were able to fulfil high volume orders at short notice in order to retain existing customers and capture new customers at attractive price points. Unlike in prior years, during Q3 or to date in Q4 2022, we have not seen any evidence of current or future significant peaks in demand. This has led management to revisit our strategy of maintaining significant levels of raw materials inventory to meet demand peaks. We now intend to expedite the sale of the vast majority of this inventory, which given current market conditions, is expected to be at lower prices. Consequently, the value of inventory has been written

down to our estimate of its net realisable value.

2. Other inventory write down ($0.9m) – we have written down the value of certain excess raw materials and work in progress following a review and an update to our relevant quality assurance policy.
3. Tri-stat inventory write down ($0.3m) – we undertook a strategic review of our Tri-stat instrument line as part of a broader review of our haemoglobins product portfolio. With annual sales of approximately $0.2m, Tri-stat is the least significant product in the portfolio. To rationalise and to simplify the haemoglobins product portfolio and to allow us to focus our resources on the higher growth products within that portfolio, management has decided to limit sales of Tri-stat to certain targeted partnerships. Consequently, management has written down the value of this inventory to reflect the consequent revised outlook.

Excluding the impact of the Q3, 2022 significant inventory excess and obsolescence charges of $4.7m, gross profit for Q3, 2022 decreased from $8.9m to $6.7m when compared to Q3, 2021. The adjusted gross margin of 34.4% for Q3, 2022 is 6.0% lower than the margin achieved in Q3, 2021, with the reduction largely due to sales mix changes, particularly the reduction in higher margin PCR VTM, inflationary increases in the price of raw materials and an under recovery of labour and overhead costs at three of our manufacturing facilities due to reduced production activity, partially driven by limited VTM production. To mitigate the impact of rising input costs, management has implemented sales price increases where appropriate. As part of our ongoing focus on simplification and efficiency and to address the under recovery of labour and overhead costs, management has reduced production headcount at two of our facilities since the end of Q3, 2022. Management is expanding the range of activities at its Jamestown, NY plant to include autoimmune product manufacturing and other activities to increase its output.

Other operating income was lower by $1.0m compared to Q3, 2021. The $1.0m other operating income in Q3, 2021 related to loan funding received under the U.S. government's Paycheck Protection Program ("PPP"). A PPP loan of $1.0m received by the Company in 2021 was forgiven during Q3, 2021 and was recognised as income in that quarter. No PPP income was recognised in 2022 as all PPP loans were forgiven in previous years.

Research and development expenses declined slightly from $1.1m to $1.0m when compared to Q3, 2021 mainly due to lower headcount. Selling, general and administrative (SG&A) expenses were $5.8m in Q3, 2022, a reduction of $0.3m compared to Q3, 2021 partially due to a continued focus on cost control measures. With the lifting of COVID related travel restrictions we have tasked our sales and marketing teams to increase travel to customers and trade shows as we continue to revitalise our sales activities. This has led to an increase in travel and marketing costs in Q3, 2022, however management believes this is a worthwhile and important investment. The strengthening of the US Dollar against the Euro this year has aided cost reductions in our Euro-denominated SG&A expenses.

Impairment charges for Q3, 2022 were $2.3m, compared to zero in Q3, 2021. Under IFRS accounting standards, companies are required to assess at the end of each reporting period whether there is any indication that an asset may be impaired. If any such indication exists, the entity is required to estimate the recoverable amount of the asset. For the period ended September 30, 2022, we determined that two internally developed products, the autoimmune smart reader and the Tri-stat instrument, which had a combined carrying value of $2.3m within intangible assets, had a recoverable amount of zero.

The development project for the autoimmune smart reader was paused earlier in 2022 as management reviewed other options, including the potential to proceed with a third-party reader instead of our own internally developed reader. Following this review, we determined that there were likely greater opportunities to capture more market share in a more capital efficient manner through partnering with a third-party reader manufacturer rather than pursuing an independent strategy. At this point in time there is significant uncertainty if we will complete the project to develop our own in-house autoimmune smart reader and thus while we may re-visit this decision in the future, in the interests of prudence we have impaired the project's carrying value. As described above, we undertook a strategic review of our Tri-stat instrument as part of a broader review of our haemoglobins product portfolio. In order to rationalise the haemoglobins product portfolio and to allow us to focus our resources on the higher growth products within that portfolio, management decided that Tri-stat sales would be restricted to only certain targeted partnerships, and this has led to an impairment in the carrying value of the Tri-stat intangible asset.

Operating loss for the quarter was $7.1m, which represents a decrease in profitability of $9.9m compared to Q3, 2021 and was attributable to a lower gross profit (including the impact of the Q3, 2022 significant excess and obsolescence charges related to inventory), lower other operating income and higher impairment charges recorded this quarter. These effects were partly offset by lower R&D and SG&A expenses.

Financial income for Q3, 2022 was $0.3m compared to $0.2m for Q3, 2021. In Q3, 2022, financial income mainly related to a fair value adjustment for the derivative liability related to warrants granted to the Group's principal lender. The financial income in Q3, 2021 was due to a fair value adjustment for the embedded derivatives in the exchangeable notes. There is no equivalent adjustment in Q3, 2022 because 99.7% of the exchangeable notes were retired in January 2022.

Financial expenses in Q3, 2022 were $2.2m compared to $1.4m in Q3, 2021, an increase of $0.8m. The interest expense relating to the senior secured term loan and the 7-year convertible note were $1.8m and $0.3m respectively in Q3, 2022. These amounts consist of both cash interest and non-cash accretion interest. As both of these borrowings are new in 2022, there was no interest expense recorded in the comparative period's results in respect of these facilities. In Q3, 2021 the cash and non-cash interest expense for the exchangeable

notes was $1.2m, which was reduced to almost zero in Q3, 2022 due to the debt re-financing earlier this year. The remainder of the financial expense in Q3, 2022 and Q3, 2021 consists of notional interest on lease liabilities for right-of-use assets, which has remained broadly stable at between $0.1m and $0.2m.

The loss after tax for continuing operations for the quarter was $8.9m in comparison to a profit of $1.3m for the equivalent period last year. This decrease in profitability is primarily due to lower gross profit, lower other operating income, higher impairment charges and higher financial expenses this quarter.

Earnings before interest, tax, depreciation, amortisation, share option expense, impairment charges and significant excess and obsolescence charges related to inventory for Q3, 2022 (Adjusted EBITDASO) was $0.8m. This is made up as follows:

	$m
Operating loss	(7.1)
Depreciation	0.5
Amortisation	0.3
Impairment charges	2.3
Significant excess and obsolescence charges related to inventory	4.7
Adjusted EBITDA	***0.7***
Share option expense	0.1
Adjusted EBITDASO	**0.8**

The basic loss per ADS for Q3, 2022 was 23.5 cents compared to a basic profit per ADS of 6.3 cents in Q3, 2021. The diluted loss per ADS for Q3, 2022 was 23.5 cents compared to a diluted profit per ADS of 6.1 cents in Q3, 2021.

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 Gross Profit, Adjusted Gross Margin, Adjusted EBITDA, 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 an IFRS and non-IFRS basis is provided in a table above.

Liquidity

The Group's cash balance decreased from $10.5m at the end of Q2, 2022 to $7.3m at the end of Q3, 2022, a decrease of $3.2m. Cash generated from operations for Q3, 2022 was $0.7m, an increase of $0.1m compared to Q3, 2021. During Q3, 2022 the Company had capital expenditure cash outflows of $1.3m (Q3, 2021: $2.0m) and payments for property leases of $0.7m (Q3, 2021: $0.7m). Interest payments in the quarter were $1.7m (Q3, 2021:

$0.0m).

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 September 30, 2022 US$000 (unaudited)**	**Three Months Ended September 30, 2021 US$000 (unaudited)**	**Nine Months Ended September 30, 2022 US$000 (unaudited)**	**Nine Months Ended September 30, 2021 US$000 (unaudited)**
Revenues	**19,502**	**22,004**	**56,742**	**73,441**

Cost of sales (including Q3, 2022 significant excess and obsolescence charges related to inventory of $4,697; 2021: $Nil)	(17,487)	(13,104)	(40,930)	(42,601)
Gross profit	**2,015**	**8,900**	**15,812**	**30,840**
Gross margin %	10.3%	40.4%	27.9%	42.0%
Other operating income	1	1,043	2	3,950
Research & development expenses	(1,023)	(1,063)	(2,972)	(3,556)
Selling, general and administrative expenses	(5,791)	(6,112)	(18,979)	(19,102)
Impairment charges	(2,288)	0	(2,808)	(6,068)
Operating (Loss)/Profit	**(7,086)**	**2,768**	**(8,945)**	**6,064**
Financial income	329	194	329	1,213
Financial expenses	(2,184)	(1,361)	(22,488)	(4,097)
Net financial expense	(1,855)	(1,167)	(22,159)	(2,884)
(Loss)/Profit before tax	**(8,941)**	**1,601**	**(31,104)**	**3,180**
Income tax (expense)/credit	(3)	(251)	177	(1,011)
(Loss)/Profit for the period on continuing operations	**(8,944)**	**1,350**	**(30,927)**	**2,169**
Loss for the period on discontinued operations	(1)	(29)	(3)	(29)
(Loss)/Profit for the period (all attributable to owners of the parent)	**(8,945)**	**1,321**	**(30,930)**	**2,140**
(Loss)/ Earnings per ADS (US cents)	(23.5)	6.3	(95.9)	10.2
Diluted (loss)/ Earnings per ADS (US cents)	(23.5)	6.1	(95.9)	9.6
Weighted average no. of ADSs used in computing basic earnings per ADS	38,107,571	20,901,703	32,261,235	20,901,703
Weighted average no. of ADSs used in computing diluted earnings per ADS	38,107,571	21,831,978	32,261,235	22,262,325

Trinity Biotech plc
Consolidated Balance Sheets

	September 30, 2022 US$ '000 (unaudited)	**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	6,082	6,261	5,634	5,918
Goodwill and intangible assets	37,144	38,743	37,320	35,981
Deferred tax assets	4,533	4,553	4,478	4,101
Derivative financial asset	147	140	219	–
Other assets	155	207	175	207
Total non-current assets	48,061	49,904	47,826	46,207
Current assets				
Inventories	23,553	29,109	29,627	29,123

Trade and other receivables	17,265	15,913	16,898	16,116
Income tax receivable	1,762	1,762	1,734	1,539
Cash, cash equivalents and deposits	7,254	10,453	10,012	25,910
Total current assets	49,834	57,237	58,271	72,688
TOTAL ASSETS	97,895	107,141	106,097	118,895
EQUITY AND LIABILITIES				
Equity attributable to the equity holders of the parent				
Share capital	1,963	1,963	1,445	1,213
Share premium	53,297	53,297	21,874	16,187
Treasury shares	(24,922)	(24,922)	(24,922)	(24,922)
Accumulated (deficit)/surplus	(17,929)	(9,103)	481	12,559
Translation reserve	(5,799)	(5,439)	(5,186)	(5,379)
Other reserves	23	23	23	23
Total equity/(deficit)	6,633	15,819	(6,285)	(319)
Current liabilities				
Trade and other payables	14,447	13,600	15,637	17,107
Income tax payable	21	21	40	22
Exchangeable note payable	210	210	210	83,312
Provisions	50	50	50	50
Total current liabilities	14,728	13,881	15,937	100,491
Non-current liabilities				
Senior secured term loan	44,143	43,990	76,246	–
Derivative financial liability	1,681	2,002	1,671	–
Convertible note	13,557	13,372	–	–
Other payables	11,818	12,723	13,279	13,865
Deferred tax liabilities	5,335	5,354	5,249	4,858
Total non-current liabilities	76,534	77,441	96,445	18,723
TOTAL LIABILITIES	91,262	91,322	112,382	119,214
TOTAL EQUITY AND LIABILITIES	97,895	107,141	106,097	118,895

Trinity Biotech plc
Consolidated Statement of Cash Flows

	Three Months Ended September 30, 2022 US$000 (unaudited)	**Three Months Ended September 30, 2021 US$000 (unaudited)**	**Nine Months Ended September 30, 2022 US$000 (unaudited)**	**Nine Months Ended September 30, 2021 US$000 (unaudited)**
Cash flows from operating activities				
(Loss)/profit for the period	(8,945)	1,321	(30,930)	2,140
Adjustments to reconcile net profit/(loss) to cash provided by operating activities:				
Depreciation	478	545	957	1,681

Amortisation	266	231	708	689
Income tax expense/(credit)	3	251	(177)	1,011
Financial income	(329)	(194)	(329)	(1,213)
Financial expense	2,184	1,361	22,488	4,097
Share-based payments	119	253	438	946
Foreign exchange gains on operating cash flows	164	101	15	34
Impairment charges	2,288	–	2,808	6,068
Excess and obsolescence charges related to inventory	4,697	–	4,697	–
Other non-cash items	(399)	(1,487)	(96)	(4,631)
Operating cash flows before changes in working capital	526	2,382	579	10,822
Net movement on working capital	153	(1,777)	(3,328)	(3,103)
Cash generated/(used) from operations	**679**	**605**	**(2,749)**	**7,719**
Interest paid	(1)	(13)	(4)	(38)
Interest received	0	1	2	3
Income taxes (paid)/received	(2)	1,104	(1)	1,224
Net cash generated/(used) by operating activities	**676**	**1,697**	**(2,752)**	**8,908**
Cash flows from investing activities				
Payments to acquire intangible assets	(1,003)	(1,686)	(4,214)	(4,974)
Acquisition of property, plant and equipment	(321)	(273)	(626)	(1,242)
Net cash used in investing activities	**(1,324)**	**(1,959)**	**(4,840)**	**(6,216)**
Cash flows from financing activities				
Issue of ordinary share capital including share premium (net of issuance costs)	–	–	25,019	–
Net proceeds from new senior secured term loan	–	–	80,014	–
Proceeds for convertible note issued	–	–	20,000	–
Expenses paid in connection with debt financing	–	–	(2,356)	–
Repayment of senior secured term loan	–	–	(34,500)	–
Penalty for early settlement of term loan	–	–	(3,450)	–
Purchase of exchangeable notes	–	–	(86,730)	–
Interest paid on senior secured term loan	(1,609)	–	(5,315)	–
Interest paid on convertible note	(75)	–	(124)	–
Proceeds from Paycheck Protection loans	–	–	–	1,764
Interest payment on exchangeable notes	(4)	–	(1,293)	(1,998)
Payment of lease liabilities	(684)	(726)	(2,184)	(2,198)
Net cash generated/(used) in financing activities	**(2,372)**	**(726)**	**(10,919)**	**(2,432)**
(Decrease)/increase in cash and cash equivalents and short-term investments	(3,020)	(988)	(18,511)	260
Effects of exchange rate movements on cash held	(179)	(154)	(145)	(112)

Cash and cash equivalents and short-term investments at beginning of period	10,453	28,617	25,910	27,327
Cash and cash equivalents and short-term investments at end of period	**7,254**	**27,475**	**7,254**	**27,475**

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).

Contact: **Trinity Biotech plc**
John Gillard
(353)-1-2769800

Lytham Partners, LLC
Joe Diaz
(1)-602-889-9700
E-mail: investorrelations@trinitybiotech.com