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Trinity Biotech Announces Q2 2024 Financial Results

-Q2, 2024 total revenues of $15.8 million grew +14% Y/Y and +7.7% Q/Q based on strong demand and output in the TrinScreen HIV business-

-Point-of-Care product revenue of $4.6 million grew 119% Y/Y and +53% Q/Q-

-Reiterating guidance to achieve approximately $20 million of annualized run-rate EBITDASO[1] on annualized run-rate revenues of approximately $75 million by Q2, 2025-

DUBLIN, Ireland (August 14, 2024)... Trinity Biotech plc (Nasdaq: TRIB), a commercial stage biotechnology company focused on human diagnostics and diabetes management solutions, including wearable biosensors, today announced the Company's results for the quarter ended June 30, 2024.

Existing Business - Key Highlights

Strong Revenue and Profitability Improvements

- Strong demand and output in TrinScreen HIV drove a 14.0% year-on-year revenue increase and 7.7% quarter-on-quarter revenue increase.
- 119% year-on-year revenue growth in our Point-of-Care ("PoC") products, with PoC delivering 53% quarter-on-quarter revenue growth.
- Continued disciplined execution on profitability enhancing initiatives contributed to:
  - a decrease in the operating loss (before restructuring and impairment charges) to $1.7 million:
    - from $4.0m in Q2, 2023, a 59% improvement, and
    - from $3.0m in Q1, 2024, a 45% improvement.
  - Based upon strong execution and continued momentum in the new management team's Comprehensive Transformation Plan (see below), the Company expects further gross margin and EBITDASO[1] improvement through 2024 and into 2025.
  - Company reiterates guidance of approximately $20 million of annualized run-rate EBITDASO[1] on annualised run-rate revenues of approximately $75 million by Q2, 2025. This outlook is predicated solely on growth from the existing businesses including haemoglobin testing and HIV, and planned improvements to operating margins, with no contribution from the recently acquired biosensor business.

Comprehensive Transformation Plan – Key Developments

- Management continues to make significant progress on the expedited execution of the profitability focused initiatives announced in early 2024:
  - Consolidate & Offshore Manufacturing:

[1] Earnings before interest, tax, depreciation, amortization, share based payments from continuing operations– also excludes impairment charges and one-off items.

        - We successfully completed the transfer of one of our rapid HIV product manufacturing processes to our offshore manufacturing partner. We are currently preparing the necessary data to support the submission to the relevant regulator to permit commercial production with our offshore partner.
        - We have made significant progress in consolidating our main Haemoglobin manufacturing activities currently carried at our Kansas City plant into two of our other existing sites. We remain on track to cease the main manufacturing at our Kansas City site by the end of 2024.
    - Optimise Supply Chain:
        - We have successfully transitioned a significant proportion of our Haemoglobins instrumentation supply chain to lower cost providers. We expect this shift will be gross margin accretive and provide meaningful working capital benefits.
    - Centralise & Offshore Corporate Services:
        - We have completed a significant amount of the knowledge transfer process to our intended outsourced partner and have informed affected staff of the impact on their roles.
        - We expect this centralised corporate services site to be live by Q4, 2024 and to start delivering net savings in Q4, 2024.

Biosensor Developments

- We continue to progress the development of our next generation Continuous Glucose Monitoring ("CGM") system in line with our previously communicated plan.
- We have engaged a world leading electronics design group, to support the design of this next generation solution, along with our internal team and other partners.
- We successfully initiated our first pre-pivotal clinical trial and expect this trial to conclude in September.
- We have received ethical approval to begin a second pre-pivotal clinical trial in Q4, 2024. This pre-pivotal clinical trial will give us further insights into the sensor optimisation pathway, and we expect to receive Competent Authority approval to commence the trial in the coming weeks. Results from both pre-pivotal trials will be applied to guide the design of the pivotal trial that will be used to apply for marketing approval in 2025.
- We continue to see significant strategic and commercial interest in our next generation solution.

Second Quarter Results (Unaudited)

Total revenues for Q2, 2024 were $15.8m compared to $13.9m in Q2, 2023, an increase of 14.0% and which consisted of the following:

	2024 Quarter 2	**2023 Quarter 2**	**Increase/ (decrease)**
	US$'000	**US$'000**	**%**
Clinical Laboratory	11,267	11,812	(4.6%)
Point-of-Care	4,576	2,086	119.4%
Total	***15,843***	***13,898***	***14.0%***

Our Point-of Care ('PoC') portfolio generated revenues of $4.6m for Q2, 2024, compared to $2.1m in Q2, 2023, an increase of 119.4%. Sales of our HIV screening test, TrinScreen HIV were $3.1m in the quarter (Nil in Q2, 2023) as we continued to see increased demand following our initial shipments in late 2023.

Our clinical laboratory revenues were $11.3m in Q2, 2024, a decrease of $0.5m or 4.6% compared to $11.8m in Q2, 2023. There was a strong performance in the quarter from our clinical chemistry portfolio which grew 20.4% year-over-year. This increase in our clinical chemistry revenues was offset by revenue decreases in our haemoglobins revenues, which were 10.8% lower year-over-year, primarily as a result of lower instrument sales in the period. The temporary decline in instrument sales is in line with expectations as we commercially reposition our instrument offering in line with our new improved diabetes column system which is now being rolled out.

Gross profit for the quarter was $5.7m, an increase of $0.7m compared to Q2, 2023. Gross margin for Q2, 2024 was 36.2%, which was in line with gross margin in Q2, 2023. As expected, we recorded improved margins in our haemoglobins division in Q2, 2024 due to the financial benefits resulting from our previously announced initiatives, namely our revised in-house manufacturing process of our key diabetes HbA1c consumable, which we fully implemented by the end of Q2, 2024.

The improved margin performance in haemoglobins this quarter was offset by the negative margin impact of the higher TrinScreen HIV revenues which are currently achieving lower-than-average gross margin returns. The higher TrinScreen revenues will continue to pressure our overall gross margin percentage in the second half of 2024 given its lower price point when compared to our other HIV rapid test, Uni-Gold, and because of reduced efficiency as we scale up production capacity of this new product. We do expect TrinScreen HIV gross margins to improve as 2024 progresses due to increased operational efficiency and the expected transfer of assembly to a lower cost manufacturing location by the end of 2024.

R&D
Research and development expenses in Q2, 2024 were $1.0m, a decrease of $0.2m compared to Q2, 2023. We capitalized $2.8m (including capitalized borrowing costs of $0.8m as required by IAS 23) for the quarter in relation to our biosensor development as we continued our development activities post our acquisition of the Waveform assets in January 2024. Our overall spend in the quarter, excluding interest costs, relating to our biosensor division was $2.2m.

SG&A
Selling, general and administrative (SG&A) expenses were $6.4m in Q2, 2024, compared to $7.9m in Q2, 2023, a decrease of $1.5m over the comparative period.

Key drivers of this lower SG&A expense include:

- Lower recurring salary costs of $0.8m in Q2, 2024 versus the comparative period, driven by headcount optimisation activities during Q3 and Q4 2023.
- Our share-based payments accounting charge was $0.9m lower in Q2, 2024 compared to Q2, 2023, due to headcount changes.
- These savings were partly offset by an unfavourable movement ($0.5m) in foreign exchange retranslation, which shifted from an FX gain of $0.1m in Q2, 2023, to an FX loss of $0.4m in Q2, 2024, largely related to the retranslation of foreign currency balances in our Brazilian subsidiary.

SG&A – Restructuring costs
As previously announced, the Company has implemented a comprehensive restructuring plan across the business to include the centralization and offshoring of corporate services and consolidation and relocation of manufacturing operations. The preparations for offshoring of corporate services are progressing well and offshoring will be live by Q4, 2024. Additionally, cessation of the main manufacturing activities in Kansas City remains on schedule and are expected to be completed by December 2024. A charge of $1.9m has been recognized in Q2, 2024 in relation to the costs associated with these restructuring activities.

An impairment charge of $0.4m was recorded in Q2, 2024 compared to an impairment charge of $10.8m in Q2, 2023. The impairment test performed as at June 30, 2024 identified that the value in use of some of our cash generating units was below the value of the carrying amount of their assets, other than inventories, accounts receivable, cash and cash equivalents and deferred tax assets as at June 30, 2024. We have therefore recorded an impairment charge in relation to the asset additions (including lease assets) that had been recorded during 2024.

Operating loss for the quarter was $4.1m, compared to an operating loss of $14.9m in Q2, 2023. The lower loss this quarter was mainly attributable to the higher impairment charges and higher non-cash share-based payments charge in Q2, 2023, and reduced overheads in Q2, 2024, as a result of cost saving initiatives.

Financial expenses in Q2, 2024 were $2.8m compared to $3.8m in Q2, 2023, a decrease of $1.0m. The financial expense for the current and comparative period are summarized in the table below.

	Q2, 2024 US$000	**Q2, 2023 US$000**
Term loan interest	3,055	2,475
Penalty for early settlement of term loan	-	905
Convertible note interest	290	277
Notional interest on lease liabilities for Right-of-use assets	150	157
Fair value movement for derivative balances related to term loan	78	9
Fair value movement on prepayment option	62	-
Accretion interest on deferred contingent consideration	25	-
Capitalization of borrowing costs	(824)	-
	2,836	**3,823**

Loss after tax on continuing operations

Loss after tax on continuing operations for the quarter was $6.8m compared to $18.3m for the equivalent period last year.

EBITDASO

Loss before interest, tax, depreciation, amortization, share option expense, impairment and restructuring costs (Adjusted EBITDASO) for continuing operations for Q2, 2024 was $1.4m, compared to $2.6m for the comparative period. This is made up as follows:

	Q2, 2024 US$000	**Q2, 2023 US$000**
Operating loss	**(4,052)**	**(14,852)**
Depreciation	(65)	305
Amortization	218	179
Impairment	446	10,815
Restructuring costs	1,939	-
Adjusted EBITDA for continuing operations	***(1,514)***	***(3,553)***
Share option expense	114	975
Adjusted EBITDASO for continuing operations	***(1,400)***	***(2,578)***

The Basic Loss per ADS for Q2, 2024 was $0.71 compared to a basic loss per ADS of $0.78 in Q2, 2023. Diluted Loss per ADS is the same as Basic Loss per ADS for both current and comparative quarters.

Liquidity

The Group's cash balance decreased from $5.8m at the end of Q1, 2024 to $5.3m at the end of Q2, 2024, a decrease of $0.5m.

Cash used by operating activities for Q2, 2024 was $1.1m (Q2, 2023: $4.4m). During Q2, 2024 the Company had investing cash outflows of $3.2m (Q2, 2023 inflow of $27.9m), the largest elements of this related to the capitalization of development of our CGM device. Interest payments in the quarter were $2m (Q2, 2023: $1.9m).

Use of Non-IFRS Financial Measures

The attached summary unaudited financial statements were prepared in accordance with International Financial Reporting Standards (IFRS). To supplement the consolidated financial statements presented in accordance with IFRS, the Company presents non-IFRS presentations of Adjusted EBITDA and Adjusted EBITDASO. The adjustments to the Company's IFRS results are made with the intent of providing both management and investors a more complete understanding of the Company's underlying operational results, trends, and performance. Non-IFRS financial measures mainly exclude, if and when applicable, the effect of share-based payments, depreciation, amortization, restructuring costs and impairment charges.

Adjusted EBITDA for continuing operations and Adjusted EBITDASO for continuing operations are presented to evaluate the Company's financial and operating results on a consistent basis from period to period. The Company also believes that these measures, when viewed in combination with the Company's financial results prepared in accordance with IFRS, provides useful information to investors to evaluate ongoing operating results and trends. Adjusted EBITDA for continuing operations and Adjusted EBITDASO for continuing operations, however, should not be considered as an alternative to operating income or net income for the period and may not be indicative of the historic operating results of the Company; nor is it meant to be predictive of potential future results. Adjusted EBITDA for continuing operations and Adjusted EBITDASO for continuing operations are not measures of financial performance under IFRS and may not be comparable to other similarly titled measures for other companies. Reconciliation between the Company's operating loss and Adjusted EBITDA for continuing operations and Adjusted EBITDASO for continuing operations are presented.

Forward-Looking Statements

This release includes statements that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Reform Act"), including but not limited to statements related to Trinity Biotech's cash position, financial resources and potential for future growth, market acceptance and penetration of new or planned product offerings, and future recurring revenues and results of operations. Trinity Biotech claims the protection of the safe harbor for forward-looking statements contained in the Reform Act. These forward-looking statements are often characterised by the terms "may," "believes," "projects," "expects," "anticipates," or words of similar import, and do not reflect historical facts. Specific forward-looking statements contained in this release may be affected by risks and uncertainties, including, but not limited to, our ability to capitalize on our purchase of the assets of Waveform, our continued listing on the Nasdaq Stock Market, our ability to achieve profitable operations in the future, the impact of the spread of COVID-19 and its variants, potential excess inventory levels and inventory imbalances at the company's distributors, losses or system failures with respect to Trinity Biotech's facilities or manufacturing operations, the effect of exchange rate fluctuations on international operations, fluctuations in quarterly operating results, dependence on suppliers, the market acceptance of Trinity Biotech's products and services, the continuing development of its products, required government approvals, risks associated with manufacturing and distributing its products on a commercial scale free of defects, risks related to the introduction of new instruments manufactured by third parties, risks associated with competing in the human diagnostic market, risks related to the protection of Trinity Biotech's intellectual property or claims of infringement of intellectual property asserted by third parties and risks related to condition of the United States economy and other risks detailed under "Risk Factors" in Trinity Biotech's annual report on Form 20-F for the fiscal year ended December 31, 2023 and Trinity Biotech's other periodic reports filed from time to time with the United States Securities and Exchange Commission. Forward-looking statements speak only as of the date the statements were made. Trinity Biotech does not undertake and specifically disclaims any *obligation to update any forward-looking statements.*

About Trinity Biotech

Trinity Biotech is a commercial stage biotechnology company focused on diabetes management solutions and human diagnostics, including wearable biosensors. The Company 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 and has recently entered the wearable biosensor industry, with the acquisition of the biosensor assets of Waveform Technologies Inc. and intends to develop a range of biosensor devices and related services, starting with a continuous glucose monitoring product. Our 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 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, 2024 US$000 (unaudited)**	**Three Months Ended June 30, 2023 US$000 (unaudited)**	**Six Months Ended June 30, 2024 US$000 (unaudited)**	**Six Months Ended June 30, 2023 US$000 (unaudited)**
Revenues	**15,843**	**13,898**	**30,547**	**28,727**
Cost of sales	(10,109)	(8,868)	(19,291)	(18,124)
Gross profit	**5,734**	**5,030**	**11,256**	**10,603**
Gross margin %	36.2%	36.2%	36.8%	36.9%
Other operating income	13	71	42	71
Research & development expenses	(991)	(1,233)	(2,080)	(2,093)
Selling, general and administrative expenses	(6,423)	(7,905)	(13,926)	(16,537)
Selling, general and administrative expenses – restructuring costs	(1,939)	-	(1,939)	-
Impairment charges	(446)	(10,815)	(446)	(10,815)
Operating loss	**(4,052)**	**(14,852)**	**(7,093)**	**(18,771)**
Financial income	-	62	55	216
Financial expenses	(2,836)	(3,823)	(3,100)	(6,374)
Net financial expense	(2,836)	(3,761)	(3,045)	(6,158)
Loss before tax	**(6,888)**	**(18,613)**	**(10,138)**	**(24,929)**
Income tax credit	131	267	64	278
Loss for the period on continuing operations	**(6,757)**	**(18,346)**	**(10,074)**	**(24,651)**
Profit for the period on discontinued operations	-	12,358	-	12,854
Loss for the period (all attributable to owners of the parent)	**(6,757)**	**(5,988)**	**(10,074)**	**(11,797)**
Loss per ADS (US cents)	(71.4)	(78.2)	(109.9)	(154.3)
Diluted loss per ADS (US cents)	(71.4)	(78.2)	(109.9)	(154.3)
Weighted average no. of ADSs used in computing basic earnings per ADS	9,465,514	7,656,673	9,168,811	7,644,252
Weighted average no. of ADSs used in computing diluted earnings per ADS	9,465,514	7,656,673	9,168,811	7,644,252

Trinity Biotech plc
Consolidated Balance Sheets

	June 30, 2024 US$ '000 (unaudited)	March 31, 2024 US$ '000 (unaudited)	December 31, 2023 US$ '000
ASSETS			
Non-current assets			
Property, plant and equipment	3,906	3,363	1,892
Goodwill and intangible assets	41,786	38,572	16,270
Deferred tax assets	2,407	2,020	1,975
Derivative financial asset	193	232	178
Other assets	79	79	79
Total non-current assets	48,371	44,266	20,394
Current assets			
Inventories	22,956	22,645	19,933
Trade and other receivables	17,471	17,319	13,901
Income tax receivable	240	299	1,516
Cash, cash equivalents and deposits	5,317	5,776	3,691
Total current assets	45,984	46,039	39,041
TOTAL ASSETS	94,355	90,305	59,435
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the parent			
Share capital	2,338	2,338	1,972
Share premium	49,944	49,944	46,619
Treasury shares	(24,922)	(24,922)	(24,922)
Accumulated deficit	(57,791)	(51,145)	(48,644)
Translation reserve	(5,701)	(5,804)	(5,706)
Equity component of convertible note	6,709	6,709	6,709
Other reserves	23	23	23
Total deficit	(29,400)	(22,857)	(23,949)
Current liabilities			
Income tax payable	283	337	279
Trade and other payables	23,074	20,527	12,802
Exchangeable senior note payable	210	210	210
Provisions	50	50	50
Lease liabilities	2,153	1,694	1,694
Total current liabilities	25,770	22,818	15,035
Non-current liabilities			
Senior secured term loan	65,809	58,674	40,109
Derivative financial liability	1,444	1,367	526
Convertible note	14,964	14,748	14,542
Lease liabilities	10,199	10,310	10,872
Other payables	1,784	1,760	-
Deferred tax liabilities	3,785	3,485	2,300
Total non-current liabilities	97,985	90,344	68,349
TOTAL LIABILITIES	123,755	113,162	83,384
TOTAL EQUITY AND LIABILITIES	94,355	90,305	59,435

Trinity Biotech plc
Consolidated Statement of Cash Flows

	Three Months Ended June 30, 2024 US$000 (unaudited)	Three Months Ended June 30, 2023 US$000 (unaudited)	Six Months Ended June 30, 2024 US$000 (unaudited)	Six Months Ended June 30, 2023 US$000 (unaudited)
Cash flows from operating activities				
Loss for the period	**(6,757)**	**(5,988)**	**(10,074)**	**(11,797)**
Adjustments to reconcile loss to cash used in operating activities:				
Depreciation	(65)	305	99	656
Amortization	218	179	745	430
Income tax credit	(131)	(267)	(64)	(278)
Financial income	-	(62)	(55)	(216)
Financial expense	2,836	3,823	3,100	6,374
Share-based payments	114	975	926	2,339
Foreign exchange loss/(gains) on operating cash flows	571	(98)	408	(187)
Impairment charges	446	10,815	446	10,815
Gain on sale of business	-	(12,718)	-	(12,718)
Other non-cash items	(55)	(65)	(208)	130
Operating cash outflows before changes in working capital	**(2,823)**	**(3,101)**	**(4,677)**	**(4,452)**
Net movement on working capital	1,674	(1,294)	(469)	(2,657)
Cash used in operations before income taxes	**(1,149)**	**(4,395)**	**(5,146)**	**(7,109)**
Income taxes received/(paid)	48	(23)	1,227	(26)
Net cash used in operating activities	**(1,101)**	**(4,418)**	**(3,919)**	**(7,135)**
Cash flows from investing activities				
Payments to acquire intangible assets	(3,095)	(413)	(4,492)	(768)
Payments to acquire financial asset	-	-	-	(700)
Net proceeds from sale of business unit	-	28,426	-	28,426
Payments to acquire trades or businesses	-	-	(12,500)	-
Acquisition of property, plant and equipment	(72)	(151)	(138)	(425)
Net cash (used)/generated in investing activities	**(3,167)**	**27,862**	**(17,130)**	**26,533**
Cash flows from financing activities				
Net proceeds from issue of share capital including share premium	-	-	(270)	-
Net proceeds from new senior secured term loan	6,500	-	28,175	5,000
Expenses paid in connection with debt financing	-	-	-	(147)
Repayment of senior secured term loan	-	(10,050)	-	(10,050)
Penalty for early settlement of term loan	-	(905)	-	(905)
Interest paid on senior secured term loan	(1,905)	(1,834)	(3,830)	(4,401)
Interest paid on convertible note	(75)	(75)	(150)	(150)
Interest paid on exchangeable notes	-	-	(4)	(4)
Payment of lease liabilities	(603)	(590)	(1,159)	(1,191)
Net cash provided by/(used in) financing activities	**3,917**	**(13,454)**	**22,762**	**(11,848)**
(Decrease)/increase in cash and cash equivalents	(351)	9,990	1,713	7,550
Effects of exchange rate movements on cash held	(108)	85	(87)	100
Cash and cash equivalents at beginning of period	5,776	4,153	3,691	6,578
Cash and cash equivalents at end of period	**5,317**	**14,228**	**5,317**	**14,228**

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).