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Trinity Biotech Announces Q1 2024 Financial Results and Reiterates Guidance

-Business performance on track to achieve approximately \$20 million of annualized run-rate EBITDASO¹ on annualized revenues of approximately \$75 million by Q2 2025-

-Strong sequential 39% Q/Q growth on Point-of-Care revenues associated with successful rollout and scaling of HIV test production-

-Disciplined execution of operational efficiencies led to 3.6 percentage point Q/Q increase in gross margin percentage with further improvements expected through 2024 and into early 2025-

DUBLIN, Ireland (May 23, 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 March 31, 2024.

Existing Business - Key Highlights

Strong Quarter-on-Quarter Revenue and Profitability Improvements

- Strong demand and output in TrinScreen HIV drove a 10% quarter-on-quarter revenue increase with 39% quarter on quarter revenue growth in Point-of-Care ("PoC").
- Continued disciplined execution on profitability enhancing initiatives contributed to:
 - a decrease in the net loss from \$5.5m in Q4, 2023 to a net loss of \$3.3m for Q1, 2024, a 40% improvement, and
 - a 62% improvement on our EBITDASO position when compared to Q4, 2023.
- Based upon strong Q1, 2024 execution and continued momentum in the new management team's Comprehensive Transformation Plan (see below), the Company expects further gross margin and EBITDASO improvement through 2024 and into early 2025.
- Company reiterates guidance of approximately \$20 million of Annualized run-rate EBITDASO¹ 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.

TrinScreen HIV Growth

¹ Earnings before interest, tax, depreciation, amortisation, share based payments from continuing operations— also excludes impairment charges and one-off items.

- 39% quarter on quarter increase in revenue from our PoC portfolio driven by increased sales of our new TrinScreen HIV product.
- Successful ramp up of TrinScreen HIV production in the quarter with sales of \$1.2m recognised in Q1, 2024.
- TrinScreen HIV revenue was dilutive to our overall gross margin percentage in Q1, 2024, as we invested in training additional staff to support the ramp up in production. However, we do expect near term improvements in gross margin over the coming two quarters with additional automation coming online in Q2, 2024 through repurposing existing equipment and further supply chain optimisations. Additional improvements in profitability are expected later in the year as we move to offshore downstream assembly.
- Total orders of \$6m for TrinScreen HIV for 2024 supply received to date, with revenue of over \$8m expected for fiscal year 2024.

Comprehensive Transformation Plan – Key Developments

- The following previously announced profitability initiatives are now contributing to improved financial performance:
 - Our revised in-house manufacturing process of our key Diabetes HbA1c consumable.
 - Reductions in headcount in late 2023 and Q1, 2024.
 - Overall supply chain optimisation.
 - Targeted price increases notified to customers in late 2023 and early 2024.
- We expect the above profitability initiatives to further contribute to improved financial performance improvements through 2024.
- In addition, we expect the launch of our improved diabetes column system, which is ongoing, to contribute to improved financial performance in 2024.

In early 2024, our new management team announced further profitability initiatives focused on delivering improved financial performance and since then the Company has made significant progress in advancing these key initiatives:

- Consolidate & Offshore Manufacturing:
 - We completed training of our identified offshore manufacturing partner’s staff in the assembly of our rapid HIV tests.
 - Significant progress in ceasing main manufacturing activities at our Kansas City manufacturing plant which currently serves our Haemoglobin business. We remain on track to have fully executed this change by the end of 2024.
- Optimise Supply Chain:
 - We prioritised optimisation of our rapid HIV supply chain, with increased volumes from TrinScreen HIV creating opportunities to negotiate with supply partners, resulting in meaningful reductions in our cost of goods.
- Centralise & Offshore Corporate Services:
 - We have substantially progressed the set-up of our centralised & offshored corporate services function. We have signed an implementation agreement with a third party outsourced partner.

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 now engaged a world leading physical & digital product design consultancy, based in London and California, to lead the design of this next generation solution.
- We are progressing technical optimisations of our glucose sensor wire.

- We have applied for ethical approval to begin a pre-pivotal clinical trial in June 2024. This pre-pivotal clinical trial will give us insights into the sensor optimisation pathway and we expect to receive ethical approval to commence the trial in the coming weeks.
- We also continue to focus on the exciting health & wellness analytical insight opportunities from our CGM's data capture capabilities and recently announced a strategic collaboration with medical artificial intelligence company PulseAI. Under this collaboration Trinity Biotech will provide a unique pool of multi-parameter CGM datasets from Waveform's existing biosensor database to PulseAI, which will be used to support the design and implementation of Trinity Biotech's AI-driven health & wellness analytics platform.
- PulseAI are experts in evidence-based medical AI and have extensive experience in scaling AI algorithm training using medical sensor datasets. PulseAI have worked in association with Mayo Clinic to train their machine learning algorithms using large-scale datasets captured across millions of patients.
- We have also strengthened our team with the appointment of Avinash Kale as Continuous Glucose Monitor Programme Director. We are very excited to welcome Avinash to Trinity Biotech and believe Avinash will be instrumental in advancing our mission of introducing intelligent wearable biosensors, including CGMs, into markets all around the globe.

First Quarter Results (Unaudited)

Total revenues for Q1, 2024 were \$14.7m compared to \$14.8m in Q1, 2023, a decrease of 0.8% and which were broken down as follows:

	2024 Quarter 1	2023 Quarter 1	Increase/ (decrease)
	US\$000	US\$000	%
Clinical laboratory	11,712	12,669	(7.6%)
Point-of-care	2,992	2,160	38.5%
Total	14,704	14,829	(0.8%)

Our PoC portfolio generated revenues of \$3.0m for Q1, 2024, compared to \$2.2m in Q1, 2023, an increase of 38.5%. Sales of our HIV screening test, TrinScreen HIV were \$1.2 million in the quarter as we shipped product to Africa following our initial shipments in December 2023. Substantial additional orders for TrinScreen HIV have been received post quarter-end, with our expected revenue for 2024 to be over \$8 million. Revenues for our other PoC products declined by 17.2% compared to Q1, 2023 driven by irregular quarter on quarter ordering patterns that characterise the HIV testing market in Africa.

Our clinical laboratory revenues were \$11.7m in Q1, 2024, a decrease of \$1.0m or 7.6% compared to \$12.7m in Q1, 2023. Our Haemoglobin revenue was 6.4% higher than in the comparative quarter of 2023. This increase in Haemoglobin revenue was more than offset by revenue decreases, primarily driven by lower lab services and autoimmune manufacturing revenue, which were down \$1.0m versus Q1, 2023. As previously reported, in early 2023 we ceased transplant testing activity at our Buffalo, New York laboratory, which drove the majority of this decline. In addition to these declines, there was a reduction of just over \$0.4m in revenues from our COVID-19 VTM products.

Gross profit for the quarter was \$5.5m which was broadly consistent with Q1, 2023. Gross margin for Q1, 2024 was 37.6%, which was the same as the gross margin in Q1, 2023. As expected, we recorded improved margins in our haemoglobins division in Q1 2024 due to:

- i) the financial benefits resulting from our previously announced haemoglobins business initiatives, namely the optimisation of our instrument manufacturing supply chain and our revised in-house manufacturing process of our key diabetes HbA1c consumable, which we fully implemented by the end of Q1 2024, and
- ii) a more favourable sales mix of higher margin haemoglobin consumables.

The improved margin performance in haemoglobins this quarter was offset by the margin impact of the higher TrinScreen HIV revenues, which are currently achieving a lower-than-average gross margin. Higher TrinScreen revenues will continue to dilute our overall gross margin percentage in the remaining quarters of 2024 given its lower price point when compared to our UniGold HIV test, but we do expect TrinScreen HIV to contribute additional gross profit as 2024 progresses due to further automation of our manufacturing process, increased operational efficiency and the expected transfer of assembly to a lower cost of manufacturing location by the end of 2024.

Additionally, over the coming quarters, we expect to realize further financial benefits of the previously announced cost saving initiatives in our haemoglobins, autoimmune and infectious diseases divisions.

R&D

Research and development expenses in Q1, 2024 were \$1.1m, an increase of \$0.2m compared to Q1 2023. We incurred \$0.7m in capitalised expenditure relating to our biosensor development as we begun development activities post our acquisition of the Waveform assets in January 2024. Our overall spend in the quarter relating to our biosensor division was \$1.3m. For the remainder of 2024 we expect to incur less than \$2.0m a quarter relating to our biosensor development.

SG&A

Selling, general and administrative (SG&A) expenses were \$7.5m in Q1, 2024, compared to \$8.6m in Q1, 2023, a decrease of \$1.1m in the quarter.

Key drivers of this lower SG&A expense include:

- Lower recurring salary and contractor costs of \$0.4m in Q1 2024 versus the comparative period, driven by headcount optimisation activities during Q3 and Q4 2023.
- Cost savings of approximately \$0.6m due to the benefits of our other cost saving initiatives in the last twelve months.
- Our share-based payments accounting charge was \$0.6m lower in Q1, 2024 compared to Q1, 2023, with the lower expense mainly due to the resignation of our former CEO in Q4, 2023.
- A favourable movement in foreign exchange retranslation gains and losses, which shifted from an FX loss of \$0.1m in Q1, 2023, to an FX gain of \$0.1m for Q1, 2024, largely related to the accounting driven requirement to mark-to-market Euro-denominated lease liabilities for right-of-use assets.
- These savings were offset by a quarter-on-quarter increase in operating expenses relating to our biosensor division of \$0.3m and higher amortisation of \$0.3m mainly due to the Waveform acquisition which occurred during Q1, 2024.

Operating Loss

Operating loss for the quarter was \$3.0m compared to an operating loss of \$3.9m in Q1, 2023, a decrease of \$0.9m or 23%. The lower loss was attributable to lower indirect costs – predominantly as a result of cost savings initiatives, lower non-cash share-based payments charge and a foreign exchange gain on lease accounting as detailed above.

Net Financial Expenses

Net financial expenses in Q1, 2024 were \$0.2m compared to \$2.4m in Q1, 2023, a decrease of \$2.2m. The reduction in net financial expense this quarter is a result of the renegotiation of the terms of our term loan (“Amended Term Loan”) with our main lender Perceptive Advisors (“Perceptive”) in January 2024. We obtained a 2.5% reduction in the base interest rate for the term loan from 11.25% to 8.75%. In accordance with IFRS accounting standards, the amendment of the term loan is treated as a loan modification, resulting in the recognition of a once-off non-cash modification gain of \$3.6m in Q1, 2024. This gain was based on the difference between the existing carrying amount of the loan as at the modification date and the revised carrying amount.

Additionally, the fair value movement of the derivative liability associated with warrants held by Perceptive resulted in a \$0.8m expense. Partially offsetting this was a revaluation of a derivative financial asset which estimates the value to the Company of being able to repay the Amended Term Loan early and potentially refinance at lower interest rate. The movement in the derivative financial asset led to financial income of \$0.1m in Q1, 2024.

Offsetting the above was an increase in the Amended Term Loan interest expense of \$0.4m. The increase in interest expense in Q1, 2024 compared to Q1, 2023 is driven by a higher outstanding loan balance, albeit at lower prevailing interest rates due to the renegotiation downwards of the interest rate on the Amended Term Loan. Other interest expenses remained broadly consistent with the prior quarter.

The financial expense for the current and comparative period are summarized in the table below.

	Q1, 2024	Q1, 2023
	US\$000	US\$000
Amended Term Loan interest	2,560	2,119
Convertible note interest	282	265
Notional interest on lease liabilities for Right-of-use assets	147	167
Fair value movement on derivative balances	841	–
IFRS modification adjustment to term loan	(3,566)	–
	264	2,551

Loss on continuing operations

Loss on continuing operations for the quarter was \$3.3m compared to a loss on continuing operations of \$6.3m in Q1, 2023 and \$5.5m in Q4, 2023.

EBITDASO

Loss before interest, tax, depreciation, amortisation, share option expense (Adjusted EBITDASO) for continuing operations for Q1, 2024 was \$1.5m, compared to \$2.0m for the comparative period. This is made up as follows:

	Q1, 2024	Q1, 2023
	US\$000	US\$000
Loss on continuing operations	(3,317)	(6,305)
Income tax expense/(credit)	67	(11)
Net financial expense	209	2,397
Depreciation	164	351
Amortisation	527	251
Adjusted EBITDA for continuing operations	(2,350)	(3,317)

Share option expense	812	1,364
<i>Adjusted EBITDASO for continuing operations</i>	(1,538)	(1,953)

Loss per Share

The basic loss per ADS for Q1, 2024 was \$0.37 compared to a basic loss per ADS of \$0.76 in Q1, 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 increased from \$3.7m at the end of Q4, 2023 to \$5.8m at the end of Q1, 2024, an increase of \$2.1m. Cash used by operations for Q1, 2024 was \$4.0m (Q1, 2023: \$2.7m). During Q1, 2024 the Company had investing cash outflows of \$14.0m (Q1, 2023: \$1.3m), the largest elements of this related to the acquisition of Waveform assets (\$12.5m) and an increase in intangible assets of \$1.4m (Q1, 2023: \$0.4m), mainly as a result of the CGM development activities since the Waveform acquisition. Interest payments in the quarter were \$2.0m (Q1, 2023: \$2.6m). Net proceeds from the January 2024 drawdown under the amended senior secured term loan credit facility with Perceptive were \$21.7m.

Excluding the recognition of a contingent liability of \$5.0m, which was recognised as part of the acquisition of the Waveform assets, the net movement on working capital was negative \$2.1m.

Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard

As previously reported in a Current Report on Form 6-K filed November 29, 2023, on November 21, 2023, the Company received a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that, for the preceding 30 consecutive business days, the market value of publicly held shares ("MVPHS") remained below the minimum \$15 million for continued inclusion on The Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(b)(3)(c) (the "MVPHS Requirement"). The Company was provided an extension of 180 calendar days, or until May 20, 2024, (the "Compliance Period") to regain compliance with the MVPHS Requirement.

On May 22, 2024, the Company received a staff determination letter (the "Determination Letter") from the Staff notifying the Company that it had not regained compliance with the MVPHS Requirement by May 20, 2024. Accordingly, and as described in the Determination Letter, unless the Company timely requests a hearing before a Hearings Panel (the "Panel"), the Company's securities would be subject to suspension/delisting. Accordingly, the Company intends to timely request a hearing before the Panel. The hearing request will automatically stay any suspension or delisting action pending the hearing and the expiration of any additional extension period granted by the Panel following the hearing. In that regard, pursuant to the Nasdaq Listing Rules, the Panel has the authority to grant an extension not to exceed November 18, 2024.

Notwithstanding the foregoing, there can be no assurance that the Panel will grant the Company an additional extension period or that the Company will ultimately regain compliance with all applicable requirements for continued listing on The Nasdaq Global Select Market.

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 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 profit/(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 presentation 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. 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 March 31, 2024 US\$000 (unaudited)	Three Months Ended March 31, 2023 US\$000 (unaudited)
Revenues	14,704	14,829
Cost of sales	(9,182)	(9,256)
Gross profit	5,522	5,573
Gross margin %	37.6%	37.6%
Other operating income	29	–
Research & development expenses	(1,089)	(860)
Selling, general and administrative expenses	(7,503)	(8,632)
Operating Loss	(3,041)	(3,919)
Financial income	55	154
Financial expenses	(264)	(2,551)
Net financial expense	(209)	(2,397)
Loss before tax	(3,250)	(6,316)
Income tax (expense)/credit	(67)	11
Loss for the period on continuing operations	(3,317)	(6,305)
Profit for the period on discontinued operations	-	496
Loss for the period (all attributable to owners of the parent)	(3,317)	(5,809)
Loss per ADS (US cents)	(37.4)	(76.1)
Diluted loss per ADS (US cents)	(37.4)	(76.1)
Weighted average no. of ADSs used in computing basic earnings per ADS	8,872,108	7,631,692
Weighted average no. of ADSs used in computing diluted earnings per ADS	8,872,108	7,631,692

Trinity Biotech plc
Consolidated Balance Sheets

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

Trinity Biotech plc
Consolidated Statement of Cash Flows

	Three Months Ended March 31, 2024 US\$000 (unaudited)	Three Months Ended March 31, 2023 US\$000 (unaudited)
Cash flows from operating activities		
Loss for the period	(3,317)	(5,809)
<i>Adjustments to reconcile loss to cash used in operating activities:</i>		
Depreciation	164	351
Amortisation	527	251
Income tax expense / (credit)	67	(11)
Financial income	(55)	(154)
Financial expense	264	2,551
Share-based payments	812	1,364
Foreign exchange gains on operating cash flows	(163)	(89)
Other non-cash items	(153)	195
	(1,854)	(1,351)
Operating cash outflows before changes in working capital		
Net movement on working capital	(2,143)	(1,364)
	(3,997)	(2,715)
Cash used in operations before income taxes		
Income taxes received/(paid)	1,178	(3)
	(2,819)	(2,718)
Cash flows from investing activities		
Payments to acquire trades or businesses	(12,500)	-
Payments to acquire intangible assets	(1,397)	(355)
Payments to acquire financial assets	-	(700)
Acquisition of property, plant and equipment	(66)	(274)
	(13,963)	(1,329)
Cash flows from financing activities		
Net proceeds from senior secured term loan	21,676	4,853
Interest paid on senior secured term loan	(1,925)	(2,567)
Interest paid on convertible note	(75)	(75)
Interest paid on exchangeable notes	(4)	(4)
Payment of lease liabilities	(556)	(599)
Transaction costs paid in relation to the issue of share capital	(270)	-
	18,846	1,608
Net cash provided by financing activities		
Increase / (decrease) in cash and cash equivalents	2,064	(2,439)
Effects of exchange rate movements on cash held	21	14
Cash and cash equivalents at beginning of period	3,691	6,578
Cash and cash equivalents at end of period	5,776	4,153

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).