Trinity Biotech Announces Q3 2024 Financial Results

Q3 2024 total revenue of $15.2 million grew +3% Y/Y based on strong demand and output in the TrinScreen HIV business

Point-of-Care product revenue of $4.3 million grew 60% Y/Y

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

Reiterates guidance to achieve 2024 sales revenue for TrinScreen HIV of approximately $10 million

DUBLIN, Nov. 15, 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 September 30, 2024.

Key Highlights and Developments

Continued Revenue and Profitability Improvements

- Year-over-year revenue growth of 3% and continued disciplined execution on our profitability enhancing initiatives contributed to a decrease in the operating loss (before restructuring and impairment charges) to $2.2 million from $4.5m in Q3 2023, a 51% improvement.
- Management continues to make significant progress on the execution of the profitability focused initiatives announced in early 2024 as part of its Comprehensive Transformation Plan, many of which are now at the final stages of execution and expected to deliver near term profitability improvements:
    - Consolidate & Offshore Manufacturing:
        - We successfully completed the transfer of our second rapid HIV product manufacturing processes to our offshore manufacturing partner and we have made submissions to the relevant international regulator to permit commercial production of both rapid HIV tests with our offshore partner. We expect offshore production to begin in Q1 2025.
        - We are also beginning the transfer of some more technical aspects of production of both of our rapid HIV tests to our offshore partner. Once in place we expect this to be gross margin-accretive.
        - We have continued to make significant progress in consolidating our main haemoglobin manufacturing activities currently carried out at our Kansas City plant into two of our other sites. We remain on track to cease our main

manufacturing activities at our Kansas City site by the end of 2024.
        - We have informed staff at our autoimmune test manufacturing site in Buffalo, New York, of our intention to consolidate the site's main manufacturing activities into our Jamestown, New York site. We expect to cease main manufacturing activities in our Buffalo site by the end of Q1 2025.
    - Centralise & Offshore Corporate Services:
        - Our new centralised corporate services site is now live across a number of functions, with additional functions expected to be added through the end of 2024.
- Based upon continued strong execution in our Comprehensive Transformation Plan, the Company reiterates its guidance of expecting to achieve approximately $20 million of annualized run-rate EBITDASO[1] based 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 and lab-based diagnostic businesses.

Diabetes CGM Developments

- We continue to progress the development of our next generation Continuous Glucose Monitoring ("CGM") solution for diabetes management in line with our previously communicated plan.
- The CGM market is already estimated to be worth over $10 billion a year and projected to grow rapidly.
- Following the successful completion of our first pre-pivotal trial, we are this week starting a second, larger, pre-pivotal trial which will provide extensive data on further developments of the sensor technology which will feed into our sensor design choices.
- We are confident that the steps we are taking, with our impressive partners, with an emphasis on a great user experience, enhanced data capture & insights, and reduced cost through more reusable components, will lead to a differentiated product and a higher value proposition.
- We continue to see strong commercial and strategic interest and are actively building and nurturing these relationships.
- Establishing strategic manufacturing & supply chain relationships with large scale premium market players to prepare for efficient & rapid scaling globally.

Business Development Update

- We recently completed two new lab-based technology acquisitions, which form an additional vertical to our long-term value creation & growth strategy:
    - EpiCapture Limited, a company developing a non-invasive test for monitoring the

risk of aggressive prostate cancer. Prostate cancer is the most common non-skin cancer among men in the U.S., with about 1 in 8 men diagnosed during their lifetime, and the cost for diagnosis and treatment is estimated at over approximately $10 billion annually. This acquisition marks Trinity Biotech's strategic expansion into the oncology diagnostics market.

- Metabolomics Diagnostics Limited, a company that has developed an innovative test, PrePsia, to accurately predict the risk of preeclampsia in pregnant women. Preeclampsia is a frequently occurring maternal health issue, impacting up to 5% of pregnancies, which can cause serious illness or death in affected mothers and babies.

We intend to commercialise both tests in our New York State Department of Health-certified Immco diagnostic reference laboratory.

Third Quarter Results (Unaudited)

Total revenue for Q3 2024 was $15.2m compared to $14.7m in Q3 2023, an increase of 3.2% and consisted of the following:

	2024 Quarter 3 US$'000	**2023 Quarter 3 US$'000**	**Increase/ (decrease) %**
Clinical Laboratory	10,836	11,981	(9.6%)
Point-of-Care	4,316	2,696	60.1%
Total	***15,152***	***14,677***	***3.2%***

Our Point-of-Care ('PoC') portfolio generated revenue of $4.3m for Q3 2024, compared to $2.7m in Q3 2023, an increase of 60.1%. Sales of our HIV screening test, TrinScreen HIV were $2.4m in the quarter (Nil in Q3 2023) as we continued to see strong demand following our initial shipments in late 2023.

Our clinical laboratory revenue was $10.8m in Q3 2024, a decrease of $1.2m or 9.6% compared to $12.0m in Q3 2023. There was a strong performance in the quarter from our clinical chemistry portfolio which grew 79.3% year-over-year. This increase in revenue was offset by a revenue decrease in our haemoglobins business, which was 17.1% lower year-over-year. This occurred due to decreased instrument sales during the period, combined with increased consumable sales in Q3 2023, which were influenced by the phasing of haemoglobin revenues from certain customers throughout 2023. The 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 $5.3m and gross margin for Q3 2024 was 35.0%. Gross margin was broadly in line with Q3 2023 when excluding stock obsolescence charges.

We continued to record improved margins in our haemoglobins division in Q3 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. The improved margin performance in haemoglobins 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 last quarter of 2024 given its lower price point when compared to our other HIV rapid test, Uni-Gold, and because of temporarily reduced efficiency as we scale up production capacity of this new product. We expect TrinScreen HIV gross margins to improve in early 2025 due to increased operational efficiency and the expected transfer of assembly to a lower cost manufacturing location.

R&D

Research and development expenses in Q3 2024 were $1.0m, a decrease of $0.2m compared to Q3 2023. We capitalized $2.1m (including capitalized borrowing costs of $0.6m as required by IAS 23) for the quarter in relation to our CGM development as we continued our development activities.

SG&A

Selling, general and administrative (SG&A) expenses were $6.5m in Q3 2024, compared to $7.7m in Q3 2023, a decrease of $1.2m over the comparative period. Key drivers of this lower SG&A expense include:

- Lower recurring salary costs of $0.7m in Q3 2024 versus the comparative period, driven by ongoing headcount optimisation activities during late 2023 and 2024.
- Our share-based payments accounting charge was $0.5m lower in Q3 2024 compared to Q3 2023, due to headcount changes.

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 offshoring of corporate services is progressing well and offshoring has already commenced in several areas and will continue to be rolled out through Q4 2024. Additionally, cessation of the main manufacturing activities in Kansas City remains on schedule and is expected to be completed by December 2024. A charge of $0.3m was recognized in Q3 2024 in relation to the costs associated with these restructuring activities.

Operating loss for the quarter was $2.6m, compared to an operating loss of $4.5m in Q3 2023. The lower loss this quarter was mainly attributable to higher gross margins combined with reduced overheads in Q3 2024, as a result of cost saving initiatives.

Financial expense costs in Q3 2024 were $3.1m compared to $2.4m in Q3 2023, an increase

of $0.7m. The financial expense for the current and comparative period are summarized in the table below.

	Q3 2024 US$000	Q3 2023 US$000
Term loan interest	3,224	1,942
Convertible note interest	292	276
Notional interest on lease liabilities for Right-of-use assets	152	151
Fair value movement on prepayment option	3	18
Accretion interest on deferred contingent consideration	14	–
Capitalization of borrowing costs	(601)	–
	3,084	**2,387**

Loss after tax on continuing operations

Loss after tax on continuing operations for the quarter was $4.8m compared to $6.7m for the equivalent period last year.

EBITDASO

Loss before interest, tax, depreciation, amortization, share-based payments, impairment and restructuring costs (Adjusted EBITDASO) for continuing operations for Q3 2024 was $1.4m, compared to $3.5m for the comparative period. This is made up as follows:

	Q3 2024 US$000	Q3 2023 US$000
Operating loss	**(2,558)**	**(4,500)**
Depreciation	260	173
Amortization	338	56
Restructuring costs	339	–
Adjusted EBITDA on continuing operations	***(1,621)***	***(4,271)***
Share-based payments	250	738
Adjusted EBITDASO on continuing operations	***(1,371)***	***(3,533)***

The basic and diluted loss per ADS for Q3 2024 was $0.46 compared to $1.55 in Q3 2023.

Liquidity

The Group’s cash balance decreased to $2.8m at the end of Q3 2024 from $5.3m at the end of Q2 2024.

Cash used by operating activities for Q3 2024 was $3.6m (Q3 2023: $4.7m). During Q3 2024 the Company had investing cash outflows of $3.1m (Q3 2023: $0.9m), the largest element of this pertained to the capitalization of the development costs of our CGM device. Interest payments in the quarter were $2.2m (Q3 2023: $1.9m).

At the Market Program

On July 12, 2024, the Company entered into an At the Market Offering Agreement with Craig-Hallum Capital Group LLC, as sales agent. As of September 30, 2024, the Company had sold 3,344,208 ADSs under the ATM Program, for aggregate gross proceeds of $7.7 million and aggregate net proceeds of approximately $7.1 million, after deducting commissions and fees.

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 characterized 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 the Waveform transaction and of our recent acquisitions, 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 September 30, 2024 US$000 (unaudited)	Three Months Ended September 30, 2023 US$000 (unaudited)	Nine Months Ended September 30, 2024 US$000 (unaudited)	Nine Months Ended September 30, 2023 US$000 (unaudited)
Revenue	**15,152**	**14,677**	**45,698**	**43,404**
Cost of sales	(9,844)	(10,397)	(29,134)	(28,521)
Gross profit	**5,308**	**4,280**	**16,564**	**14,883**
Gross margin %	35.0%	29.2%	36.2%	34.3%
Other operating income	–	70	42	141
Research & development expenses	(1,010)	(1,169)	(3,090)	(3,262)
Selling, general and administrative expenses	(6,517)	(7,681)	(20,443)	(24,217)
Selling, general and administrative expenses – restructuring costs	(339)	–	(2,278)	–
Impairment charges	–	–	(446)	(10,815)
Operating loss	**(2,558)**	**(4,500)**	**(9,651)**	**(23,270)**
Financial income	848	389	903	605
Financial expense	(3,084)	(2,387)	(6,184)	(8,761)
Net financial expense	(2,236)	(1,998)	(5,281)	(8,156)
Loss before tax	**(4,794)**	**(6,498)**	**(14,932)**	**(31,426)**
Income tax credit/(expense)	35	(222)	99	56
Loss for the period on continuing operations	**(4,759)**	**(6,720)**	**(14,833)**	**(31,370)**
(Loss)/profit for the period on discontinued operations	–	(1)	–	12,853
Loss for the period (all attributable to owners of the parent)	**(4,759)**	**(6,721)**	**(14,833)**	**(18,517)**
Basic loss per ADS (USD)	(0.46)	(0.88)	(1.55)	(2.42)
Diluted loss per ADS (USD)	(0.46)	(0.88)	(1.55)	(2.42)
Weighted average no. of ADSs used in computing basic earnings per ADS	10,387,099	7,665,514	9,577,871	7,651,417
Weighted average no. of ADSs used in computing diluted earnings per ADS	10,387,099	7,665,514	9,577,871	7,651,417

Trinity Biotech plc
Consolidated Balance Sheets

	September 30, 2024 US$ '000 (unaudited)	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	3,767	3,906	3,363	1,892
Goodwill and intangible assets	46,673	41,786	38,572	16,270
Deferred tax assets	694	2,407	2,020	1,975
Derivative financial asset	190	193	232	178
Other assets	43	79	79	79
Total non-current assets	51,367	48,371	44,266	20,394
Current assets				
Inventories	21,804	22,956	22,645	19,933
Trade and other receivables	21,209	17,471	17,319	13,901
Income tax receivable	226	240	299	1,516
Cash, cash equivalents and deposits	2,840	5,317	5,776	3,691
Total current assets	46,079	45,984	46,039	39,041
TOTAL ASSETS	97,446	94,355	90,305	59,435
EQUITY AND LIABILITIES				
Equity attributable to the equity holders of the parent				
Share capital	2,377	2,338	2,338	1,972
Share premium	57,519	49,944	49,944	46,619
Treasury shares	(24,922)	(24,922)	(24,922)	(24,922)
Accumulated deficit	(62,300)	(57,791)	(51,145)	(48,644)
Translation reserve	(5,748)	(5,701)	(5,804)	(5,706)
Equity component of convertible note	6,709	6,709	6,709	6,709
Other reserves	23	23	23	23
Total deficit	(26,342)	(29,400)	(22,857)	(23,949)
Current liabilities				
Income tax payable	333	283	337	279
Trade and other payables	25,308	23,074	20,527	12,802
Exchangeable senior note payable	210	210	210	210
Provisions	50	50	50	50
Lease liabilities	2,153	2,153	1,694	1,694
Total current liabilities	28,054	25,770	22,818	15,035
Non-current liabilities				
Senior secured term loan	66,441	65,809	58,674	40,109
Derivative financial liability	596	1,444	1,367	526
Convertible note	15,181	14,964	14,748	14,542
Lease liabilities	9,730	10,199	10,310	10,872

Other payables	1,798	1,784	1,760	–
Deferred tax liabilities	1,988	3,785	3,485	2,300
Total non-current liabilities	95,734	97,985	90,344	68,349
TOTAL LIABILITIES	123,788	123,755	113,162	83,384
TOTAL EQUITY AND LIABILITIES	97,446	94,355	90,305	59,435

Trinity Biotech plc
Consolidated Statement of Cash Flows

	Three Months Ended September 30, 2024 US$000 (unaudited)	**Three Months Ended September 30, 2023 US$000 (unaudited)**	**Nine Months Ended September 30, 2024 US$000 (unaudited)**	**Nine Months Ended September 30, 2023 US$000 (unaudited)**
Cash flows from operating activities				
Loss for the period	**(4,759)**	**(6,721)**	**(14,833)**	**(18,517)**
Adjustments to reconcile loss to cash used in operating activities:				
Depreciation	260	173	359	829
Amortization	338	56	1,082	486
Income tax (credit)/expense	(35)	222	(99)	(56)
Financial income	(848)	(389)	(903)	(605)
Financial expense	3,084	2,387	6,184	8,761
Share-based payments	250	738	1,176	3,078
Foreign exchange (gain)/loss on operating cash flows	(107)	40	301	(147)
Impairment charges	–	–	446	10,815
Gain on sale of business	–	–	–	(12,718)
Excess inventory obsolescence charges		932	–	932
Other non-cash items	57	(178)	(149)	(50)
Operating cash outflows before changes in working capital	**(1,760)**	**(2,740)**	**(6,436)**	**(7,192)**
Net movement on working capital	(1,880)	(2,327)	(2,349)	(4,984)
Cash outflow from operating activities before income taxes	**(3,640)**	**(5,067)**	**(8,785)**	**(12,176)**
Income tax benefit received	16	403	1,243	377
Net cash outflow from operating activities	**(3,624)**	**(4,664)**	**(7,542)**	**(11,799)**
Cash flows from investing activities				
Payments to acquire intangible assets	(2,589)	(492)	(7,080)	(1,260)
Payments to acquire financial assets	–	–	–	(700)

Net proceeds from sale of business unit	–	(266)	–	28,160
Payments to acquire trades or businesses	(403)	–	(12,903)	–
Acquisition of property, plant and equipment	(110)	(128)	(248)	(553)
Net cash (outflow)/inflow from investing activities	**(3,102)**	**(886)**	**(20,231)**	**25,647**
Cash flows from financing activities				
Net proceeds from issue of share capital including share premium	7,117	–	6,847	–
Net proceeds from new senior secured term loan	–	–	28,175	5,000
Expenses paid in connection with debt financing	–	–	–	(147)
Repayment of senior secured term loan	–	–	–	(10,050)
Penalty for early settlement of term loan	–	–	–	(905)
Interest paid on senior secured term loan	(2,116)	(1,781)	(5,947)	(6,181)
Interest paid on convertible note	(75)	(75)	(225)	(225)
Interest paid on exchangeable notes	(4)	(4)	(8)	(8)
Payment of lease liabilities	(678)	(571)	(1,838)	(1,763)
Net cash inflow/(outflow) from financing activities	**4,244**	**(2,431)**	**27,004**	**(14,279)**
Decrease in cash and cash equivalents	(2,482)	(7,981)	(769)	(431)
Effects of exchange rate movements on cash held	5	14	(82)	114
Cash and cash equivalents at beginning of period	5,317	14,228	3,691	6,578
Cash and cash equivalents at end of period	**2,840**	**6,261**	**2,840**	**6,261**

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