Trinity Biotech Announces Q1 2023 Financial Results

DUBLIN, Ireland, July 06, 2023 — 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 March 31, 2023.

Summary Highlights:

Revenue/Margin:

- Total revenue for fiscal Q1, 2023 was $17.2m. Excluding our Covid focused PCR Viral Transport Media ("VTM") products and Fitzgerald Industries (which was disposed in April 2023), revenue for the quarter of $14m was 2.0% higher than in Q1, 2022.
- Our performance in the quarter was led by year over year growth of approximately 35%, 15% and 10% respectively for our Autoimmune, Clinical Chemistry and diabetes HbA1c consumable products. Strong demand from key accounts and a focus on clearing order backlogs drove an increase of over 80% in revenues for US Autoimmune products compared to Q1, 2022 and an approximately 45% increase in deliveries for diabetes consumables in Brazil compared to Q1, 2022. Partly offsetting these revenue gains are lower revenues from low margin diabetes instrument deliveries, compared to Q1 2022. Diabetes instrument placements were up approximately 17% in Q1, 2023 vs Q4, 2022.
- Gross margin, excluding Fitzgerald Industries, was broadly flat compared to Q1, 2022 but reflected an approximately 4-point improvement over Q4 2022 as we increase prices and stabilize our manufacturing and supply chain processes.

Haemoglobins:

- We continue to work closely with the FDA to gain clearance of our 510(k) submission for the Premier Resolution Haemoglobin Variants instrument. In addition to a US market introduction in the second half of the year, we expect FDA approval will drive significant global order activity.
- The development of the next generation of our flagship diabetes HbA1c instrument, the Premier 9210, is on track for an expected roll-out in 2024. The instrument is expected to feature an improved, backward compatible reagent column system that should feature up to 3 times the injection capacity and stability, limited calibration, improved user interface and lab system integration. This is the first step of a multi-generational product development plan aimed at expanding the target market, driving lower service downtime and cost, while significantly expanding operating margins.
- China and Brazil are markets of particular focus for both product lines as we assess increasing our footprint in both markets to drive cost competitiveness, streamline regulatory pathways and expand market access.

TrinScreen HIV:

- The Company is focused on executing on the launch and distribution of its TrinScreen HIV screening test, following the announcement by the Kenyan Ministry of Health of the adoption of the new HIV rapid testing algorithm. This algorithm establishes Trinity Biotech's TrinScreen HIV as the standard screening test in Kenya under World Health Organisation ("WHO") guidelines.
- The Kenyan government is currently addressing legal challenges to the HIV testing algorithm changes and we expect to receive significant orders in the second half of 2023 upon resolution of these legal matters.
- The Kenyan HIV screening program is one of the largest in Africa, with an estimated 7 million to 9 million screening tests annually.

Portfolio Transformation & Capital Structure:

- In April, the Company completed the sale of its Fitzgerald Industries division, generating approximately $30M of proceeds that were partially used to further reduce debt by approximately $10M.
- This exit is the first of several strategic moves aimed at focusing the current portfolio around our core Haemoglobins and HIV franchises, streamlining our cost structure, reducing debt and providing firepower for M&A.
- Our pipeline of attractive M&A opportunities is aimed at disruptive adjacencies with Total Addressable Markets (TAMs) that matter, provide access to next generation diagnostic product platforms and where we can leverage our global manufacturing and distribution footprint.
- In February, the Company secured a $20 million flexible term-facility specifically to provide the ability to move quickly when opportunistic transactions arise.

Structural & Operational Initiatives:

- Multiple initiatives are underway to significantly reduce cost of goods sold in our core Haemoglobins and HIV franchises. Instrument and consumables design updates, supply chain optimization and outsourced/localized manufacturing are initiatives all aimed at driving significantly higher operating margins for these platforms.

AACC:

- Trinity Biotech will participate in the American Association of Clinical Chemistry (AACC) annual scientific meeting and clinical lab expo which takes place in Anaheim, CA from July 23 -27.

First Quarter Results (Unaudited)

The results of the Fitzgerald Industries life sciences supply business, which was disposed of

on April 27, 2023, have been reported separately as discontinued operations in the Consolidated Income Statements for all periods presented, and the assets and liabilities attributable to Fitzgerald Industries are separately presented within “Assets included in disposal group held for sale” and “Liabilities included in disposal group held for sale”, respectively, in the Consolidated Balance Sheet at March 31, 2023.

Total revenues for Q1, 2023 were $14.8m which compares to $15.7m in Q1, 2022, a decrease of 5.4% and which were broken down as follows:

	2023 Quarter 1 US$’000	**2022 Quarter 1 US$’000**	**Increase/ (decrease) %**
Clinical Laboratory	12,669	13,511	(6.2%)
Point-of-Care	2,160	2,164	(0.2%)
Total	***14,829***	***15,675***	***(5.4%)***

Clinical Laboratory revenues were $12.7m, compared to $13.5m in Q1, 2022, representing a decrease of $0.8m or 6.2%. This decrease is due to a reduction of approximately $1.2m in revenues from our PCR VTM products compared to Q1, 2022. Sales volumes for PCR VTM products have continued to decrease due to a significant scaling down of PCR testing programs for COVID-19.

Partly offsetting the reduction in revenues from our PCR VTM products were solid performances across our autoimmune and clinical chemistry products, which showed over 35% and over 15% year on year growth respectively. While our diabetes consumables revenues grew almost 10% year on year, we recorded lower instrument placement revenues which is driven by pricing changes made in late 2022 to counteract supply chain cost increases we have faced. We are significantly reorganising and optimising our supply chain to allow us reduce the price of our instrument. As such, we expect revenues from this business to continue a strong growth trend later in 2023 driven by a higher instrument installed base and operational and strategic supply chain changes, which we expect will drive opportunities for both competitive pricing optimisation and margin increase.

Point-of-Care revenues for Q1, 2023 were $2.2m which was in line with Q1, 2022, with a decrease of just 0.2%.

In Q1, 2023, gross profit was $5.6m, equating to a gross margin of 37.6%. In Q1, 2022, gross profit amounted to $6.0m equating to a gross margin of 38.2%. The reduction in gross profit is largely due to the lower sales activity. We are continuing to see the benefit of price increases and cost optimisation initiatives implemented in mid to late 2022, with the 37.6% gross margin in Q1, 2023 being higher than the Q4, 2022 like-for-like margin of 33.4% (excluding the results for Fitzgerald).

Research and development expenses declined slightly from $1.0m in Q1, 2022 to $0.9m

when compared to Q1, 2023, mainly due to lower headcount and continued focus on cost control measures.

Selling, general and administrative (SG&A) expenses were $8.6m in Q1, 2023, compared to $6.2m in Q1, 2022. A significant element of the $2.4m increase relates to:

- A higher IFRS driven non-cash share-based payments accounting charge, which increased by $1.2m in Q1, 2023 compared to Q1, 2022, due to options granted since Q1, 2022.
- An increase in foreign exchange loss largely related to the accounting driven requirement to mark-to-market Euro-denominated lease liabilities for right-of-use assets. In Q1, 2022, the foreign exchange gain on leases was $0.1m while in Q1, 2023, a foreign exchange loss of $0.2m was recorded, resulting in an unfavourable quarter-on-quarter variance of $0.3m.

Excluding the impact of the accounting-driven share-based payments expense and the foreign exchange loss on lease liabilities, the remaining increase in SG&A expenses included the following:

- Higher salary costs as a result of senior hires made in late 2022 as part of our continued development of a world class leadership team that can lead the transformation of Trinity Biotech into a high growth, efficient and agile organisation.
- A continued increase in travel costs post COVID-related travel restrictions, as our sales and marketing teams travel to customers and trade shows as we continue to revitalise our sales activities. Similarly, some key functional leaders based in Ireland have resumed visits to our overseas facilities as we seek to drive operational efficiencies. All of this has led to an increase in travel costs in Q1, 2023, compared to Q1, 2022, of approximately $0.2m. Management believes this is a worthwhile and important investment, but we do not expect the level of travel to stay at this level going forward.
- Savings on non-recurring transactional costs incurred in Q1, 2022 of $0.5m were offset by higher legal and professional fees for due diligence, corporate development and corporate finance activities as we continue to assess strategic opportunities for inorganic growth and balance sheet optimisation.

The SG&A expenses of $8.6m in Q1, 2023, represent a $1.0m reduction on the $9.6m recorded in Q4, 2022.

Operating loss for the quarter was $3.9m, compared to an operating loss of $1.2m in Q1, 2022. The higher loss was attributable to the lower revenues, and higher indirect costs – predominantly the higher non-cash share-based payments charge and foreign exchange loss on lease accounting as detailed above. Excluding the impact of higher non-cash share based payment charges and foreign exchange loss on lease accounting the operating loss was $2.4m.

Financial income for Q1, 2023 was $0.2m compared to $0.2m for Q1, 2022, and mainly related to fair value adjustments for the derivative liability related to warrants granted to the Group's principal lender.

Financial expenses in Q1, 2023 were $2.6m compared to $12.2m in Q1, 2022, a decrease of $9.7m. The financial expense for the current and comparative period are summarized in the table below.

	Q1, 2023 US$'m	Q1, 2022 US$'m
Loss on disposal of Exchangeable Notes	–	9.7
Term loan interest	2.1	2.0
Convertible note interest	0.3	–
Exchangeable note interest	–	0.4
Notional interest on lease liabilities for Right-of-use assets	0.2	0.2
Other	–	–
	2.6	**12.2**

Note: table contains rounded numbers.

The comparative period included a loss on disposal of the Exchangeable Notes of $9.7m. In January 2022, the Company retired approximately $99.7m of the Exchangeable Notes. The accounting measure of total consideration for the retirement of the Exchangeable Notes was $92.9m, consisting of cash consideration of $86.7m and the issuance of ADSs with a market value at the date of issue of $6.2m. The Exchangeable Notes were treated as a host debt instrument under IFRS with embedded derivatives attached. The embedded derivatives related to a number of put and call options which were measured at fair value in the Income Statement. On initial recognition in 2015, the host debt instrument was recognised at the residual value of the total net proceeds of the bond issue less fair value of the embedded derivatives. Subsequently, the host debt instrument was measured at amortised cost using the effective interest rate method. At the date of disposal, the carrying value of the extinguished Exchangeable Notes was $83.2m. As the IFRS measure of consideration was higher by $9.7m, the resulting loss on disposal was recorded as a once-off charge in the Income Statement in Q1, 2022.

Excluding this non-recurring financial expenses, financial expenses for Q1, 2022, were $2.5m, compared to $2.6m in Q1, 2023. With the exception of $0.2m, Exchangeable Notes with a fixed coupon rate of 4.0% were extinguished in late January, 2022, and replaced by the senior secured term loan of $81.3m with a variable coupon which averaged 13% for February and March, 2022. While the principal on the senior secured notes was reduced following the partial settlement of $34.5m in May 2022, a further $5m was drawn down in February 2023 and the variable coupon increased to an average of 16% in Q1, 2023. As previously announced, in connection with the disposal of the Fitzgerald Industries life sciences supply

business, the Company used approximately $11 million of the proceeds of the sale to repay approximately $10.1 million of its senior secured debt, plus an approximate $900,000 early repayment penalty.

The 7 year convertible note had not been drawn down at March 31, 2022 and as such there was no interest expense recorded in the comparative period's result on that facility.

The loss after tax for continuing operations for the quarter was $6.3m in comparison to a loss of $13.1m for the equivalent period last year. The variance is due to lower net financial expenses due to the loss on disposal of the Exchangeable Notes in Q1, 2022 partly offset by lower revenues and higher indirect costs in Q1, 2023. The profit for the period on discontinued operations of $0.5m in Q1, 2023, compared to $0.8m in Q1, 2022, predominantly relates to the net result of the Fitzgerald Industries life sciences supply business which has been disposed in April 2023.

Loss before interest, tax, depreciation, amortisation, share option expense, and impairment charges for continuing operations for Q1, 2023 (Adjusted EBITDASO) was $2.0m. This is made up as follows:

	$m
Operating loss	(3.9)
Depreciation	0.3
Amortisation	0.3
Adjusted EBITDA for continuing operations	***(3.3)***
Share option expense	1.4
Adjusted EBITDASO for continuing operations	**(2.0)**

Note: table contains rounded numbers.

The basic loss per ADS for Q1, 2023 was $0.15 compared to a basic loss per ADS of $0.50 in Q1, 2022. Diluted Loss per ADS is the same as Basic Loss per ADS for both current and comparative quarters.

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, significant excess and obsolescence charges related to inventory, 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.

Liquidity

The Group's cash balance decreased from $6.6m at the end of Q4, 2022 to $4.2m at the end of Q1, 2023, a decrease of $2.4m. For clarity, the cash balance of $4.2m includes the cash balance of Fitzgerald at the end of Q1, 2023. Cash used by operations for Q1, 2023 was $2.7m (Q1, 2022: $1.5m). During Q1, 2023 the Company had investing cash outflows of $1.3m (Q1, 2022: $1.7m) and payments for property leases of $0.6m (Q1, 2022: $0.8m). Interest payments in the quarter were $2.6m (Q1, 2022: $3.1m). Net proceeds from the February 2023 drawdown under the amended and restated senior secured term loan credit facility with Perceptive Advisors were $4.9m. As previously announced, the disposal of the Fitzgerald Industries life sciences supply business, for cash proceeds of approximately $30 million subject to customary adjustments, allows the Company to reduce its debt servicing costs and provide capital for growth, transformation, and potentially further debt reduction.

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 March 31, 2023 US$000 (unaudited)**	**Three Months Ended March 31, 2022 US$000 (unaudited)**
Revenues	**14,829**	**15,675**
Cost of sales	(9,256)	(9,693)
Gross profit	**5,573**	**5,982**
Gross margin %	37.6%	38.2%
Other operating income	–	1
Research & development expenses	(860)	(965)
Selling, general and administrative expenses	(8,632)	(6,234)
Operating Loss	**(3,919)**	**(1,216)**
Financial income	154	218
Financial expenses	(2,551)	(12,222)
Net financial expense	(2,397)	(12,004)
Loss before tax	**(6,316)**	**(13,220)**
Income tax credit	11	150
Loss for the period on continuing operations	**(6,305)**	**(13,070)**
Profit for the period on discontinued operations	496	791
Loss for the period (all attributable to owners of the parent)	**(5,809)**	**(12,279)**
Loss per ADS (US cents)	(15.2)	(50.0)

Diluted loss per ADS (US cents)	(15.2)	(50.0)
Weighted average no. of ADSs used in computing basic earnings per ADS	38,158,460	24,575,333
Weighted average no. of ADSs used in computing diluted earnings per ADS	38,158,460	24,575,333

Trinity Biotech plc

Consolidated Balance Sheets

	March 31, 2023 US$ '000 (unaudited)	December 31, 2022 US$ '000
ASSETS		
Non-current assets		
Property, plant and equipment	5,496	5,682
Goodwill and intangible assets	21,330	35,269
Financial asset[1]	1,500	–
Deferred tax assets	4,297	4,218
Derivative financial asset	152	128
Other assets	120	139
Total non-current assets	32,895	45,436
Current assets		
Assets included in disposal group held for sale	17,746	–
Inventories	21,532	22,503
Trade and other receivables	13,594	15,753
Income tax receivable	1,858	1,834
Cash, cash equivalents and deposits	3,532	6,578
Total current assets	58,262	46,668
TOTAL ASSETS	91,157	92,104
EQUITY AND LIABILITIES		
Equity attributable to the equity holders of the parent		
Share capital	1,967	1,963
Share premium	46,532	46,458
Treasury shares	(24,922)	(24,922)
Accumulated deficit	(31,140)	(26,695)
Translation reserve	(5,787)	(5,775)
Equity component of convertible note	6,709	6,709
Other reserves	23	86
Total deficit	(6,618)	(2,176)
Current liabilities		
Liabilities included in disposal group held for sale	1,386	–
Income tax payable	33	28

Trade and other payables	12,910	15,375
Exchangeable senior note payable	210	210
Provisions	50	50
Lease liabilities	1,561	1,676
Total current liabilities	16,150	17,339
Non-current liabilities		
Senior secured term loan	49,199	44,301
Derivative financial liability	1,517	1,569
Convertible note	13,936	13,746
Lease liabilities	12,026	12,267
Deferred tax liabilities	4,947	5,058
Total non-current liabilities	81,625	76,941
TOTAL LIABILITIES	97,775	94,280
TOTAL EQUITY AND LIABILITIES	91,157	92,104

[1] The Group's investment commitment of $1.5m in imaware, Inc. represents an investment in unquoted convertible equity instruments. As the instruments do not have a quoted price in an active market for an identical instrument, the determination of fair value involves use of appropriate valuation methods and certain unobservable inputs, requires significant management judgement and estimation, and may change over time. The valuation may be subject to a wide range of possible fair value measurements, and may fluctuate significantly due to changes in market variables, as well as available entity specific information.

Trinity Biotech plc
Consolidated Statement of Cash Flows

	Three Months Ended March 31, 2023 US$000 (unaudited)	**Three Months Ended March 31, 2022 US$000 (unaudited)**
Cash flows from operating activities		
Loss for the period	(5,809)	(12,279)
Adjustments to reconcile loss to cash used in operating activities:		
Depreciation	351	432
Amortisation	251	228
Income tax credit	(11)	(150)
Financial income	(154)	(218)
Financial expense	2,551	12,222
Share-based payments	1,364	197
Foreign exchange (gains)/losses on operating cash flows	(89)	42
Other non-cash items	195	(691)

Operating cash outflows before changes in working capital	**(1,351)**	**(217)**
Net movement on working capital	(1,364)	(1,263)
Cash used in operations before income taxes	**(2,715)**	**(1,480)**
Income taxes paid	(3)	(13)
Net cash used in operating activities	**(2,718)**	**(1,493)**
Cash flows from investing activities		
Payments to acquire intangible assets	(355)	(1,553)
Payments to acquire financial assets	(700)	–
Acquisition of property, plant and equipment	(274)	(162)
Net cash used in investing activities	**(1,329)**	**(1,715)**
Cash flows from financing activities		
Net proceeds from new senior secured term loan	4,853	80,015
Expenses paid in connection with debt financing	–	(2,316)
Purchase of exchangeable notes	–	(86,730)
Interest paid on senior secured term loan	(2,567)	(1,786)
Interest paid on convertible note	(75)	–
Interest payment on exchangeable notes	(4)	(1,285)
Payment of lease liabilities	(599)	(770)
Net cash provided by/(used in) financing activities	**1,608**	**(12,872)**
Decrease in cash and cash equivalents	(2,439)	(16,080)
Effects of exchange rate movements on cash held	14	182
Cash and cash equivalents at beginning of period	6,578	25,910
Cash and cash equivalents at end of period	**4,153**	**10,012**

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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