RNS Number: 3161W Verici Dx PLC 15 July 2024

Verici Dx plc ("Verici Dx" or the "Company")

Half-year report

Continued strategic delivery with revenues

Verici Dx plc (AIM: VRCI), a developer of advanced clinical diagnostics for organ transplant, announces its unaudited interim results for the six months ended 30 June 2024 ("H1 2024"). Comparative data is for the unaudited six months ended 30 June 2023 ("H1 2023") unless stated otherwise.

Focus on three distinct revenue streams

The Company has transitioned from a purely research stage business to one with three distinct revenue streams: licensing revenues, direct sales, and other income from our Services Business. In the period, this resulted in total revenues of \$3.3m (FY23: \$1.0m):

- Licensing revenues. Recognition of revenue during H1 2024 relating to the successful achievement of transfer of the pre-transplant prognostic testing technology (formerly known as Clarava[™]). This is in accordance with the terms of a global licensing and commercialisation agreement with Thermo Fisher announced on 15 November 2023 (the "Thermo Agreement").
- Direct sales. The Company is seeing increased test adoption with our first product, Tutivia[™]. This is now being used in fifteen centres in the US, and this is growing as anticipated. Although the timing of revenue recognition from these sales is impacted by the various reimbursement processes, the adoption is in line with our expectations and now supported by additional hires in our commercial team.
- Services income. This recognises the value in the data asset, collaborations, and other applications of the Company's technology and expertise. Collectively, the Company is managing these as our Services Business. In the period, the successful completion of final deliverables relating to urine samples in accordance with the Thermo Agreement generated revenues. This is in addition to the revenues generated in 2023.

Each of these income streams is further supported going forward by our newly expanded, in-house bioinformatics capability which supports further product development and commercialisation, as well as identifying and underpinning additional value in the Company's research assets.

Significant progress across our lead products

The Company has continued to make significant progress with each of its lead products:

- Submitted the Technical Assessment ("TA") File for Tutivia[™], an important step in the pathway for reimbursement coverage from Medicare. We are currently in a period of review and expect to have a Medicare determination by the end of 2024.
- Presented new performance data on Tutivia[™] in the setting of delayed graft function ("DGF") where there is unmet clinical need and generated interest from practitioners at the June American Transplant Congress ("ATC") meeting. The subsequent increase in adoption reflects in part interest in using Tutivia[™] in this context.
- Development of the Company's third product, Protega[™], is on track with additional funding supporting the ability to generate more robust data / better commercialisation outcomes. The first validation data is expected in H1 2025.
- Initiated a new key opinion leader (KOL) led education program to highlight the uses and advantages
 of the Company's underlying technology and its application in the lead products.

Continued and consistent strong delivery against multiple operational milestones

The Company has established a strong track record of delivery across multiple projects and initiatives, and we are pleased this has continued throughout the first half of 2024:

- Finalised the CLIA application for the final US state, New York, where there were several additional stages to complete prior to accreditation compared to the process in other states. When granted, the Company's laboratory will be able to test samples from patients across all US states.
- Launched an interactive patient-focused educational tool, the Patient Journey, providing a detailed overview of all stages of the kidney transplant journey. This aligns with the Company's goal to enhance patient care and support by ensuring that patients and caregivers have access to the latest information and best practices for kidney transplant care.
- Gained accreditation from the internationally recognised College of American Pathology (CAP) for the
 testing laboratory in Franklin, TN, USA. Along with the existing CLIA Certificate of Compliance for the
 Company's clinical laboratory in Nashville, TN, USA, this further reinforcesthe Company's on-going
 commitment to maintaining best in class quality systems.
- Announced an exciting collaboration with The Westmead Institute for Medical Research based in Sydney, Australia, on a newly awarded, 4-year federal research grant. The goal of the research is to enhance the prediction and management of risks associated with organ transplants across a diverse group of patients drawn from three different clinical sites.

Financial highlights

- Revenue of \$3.3m (H1 2023: \$-; FY 2023: \$1.0m).
- EBITDA loss of \$1.1m (H1 2023: loss of \$4.9m; FY 2023: loss of \$8.0m).
- \$7.0m cash balance as at 30 June 2024 (31 December 2023: \$2.6m).
- Net cash outflow from operating activities in H1 2024 was \$3.2m (H1 2023: \$4.8m outflow; FY 2023: \$7.2m outflow).
- Equity fundraise of £6.5m (\$8.2m) in total gross proceeds (£6.0m / \$7.5m net) through the issue of 72,222,222 new ordinary shares.

The financial effects of the Thermo Agreement and the equity fundraise, together with our business modelling assumptions which remain unchanged, mean that the Company's cash runway now extends into 2026.

Strategic update and outlook

At the time of the equity fundraise in early 2024, we set out our strategic priorities. The team has continued to deliver strong progress against each of these areas and is confident regarding the outlook for each of these areas.

- Licensing revenues. There will be royalties from tests sold after Thermo Fisher launches its pretransplant test and a further milestone payment upon achievement of a commercial milestone by Thermo Fisher.
- Direct revenues. With our expanded sales force now in situ, we are seeing momentum both with the number of centres adopting Tutivia[™] as well repeat orders as the test becomes embedded in their processes. The timing of when revenue can be recognised is affected by the LCD coverage determination.
- Other products. Protega[™] is progressing through the phases of its clinical development and, in the
 event of successful validation, will have commercialisation opportunities through either licensing or
 direct routes. Longer term, there remains scope to move into adjacent disease areas, including other
 transplant organs and other conditions.
- Other applications of the Company's approach, expertise and technology. The value inherent in the
 Services Business has already been demonstrated through the urine element of the Thermo
 Agreement. Other opportunities to create value within the Services Business are currently at various
 stages of negotiation.

Sara Barrington, Chief Executive Officer of Verici Dx, said:

"This has been another busy period, with the focus of the business upon revenue generation from our three separate income streams together with the delivery of many significant commercial and operational milestones. I am delighted with the progress from the team and welcome the increased pace that the fundraise enabled."

"The steps we took at the start of the year to bolster our balance sheet positioned us well to progress our strategic ambitions. The focus through the remainder of 2024 remains to advance multiple growth and value creation initiatives over the short, medium and longer term, whilst maintaining our strong financial discipline. I am pleased with the strong start we have made across these multiple revenue generation initiatives, and we will continue to update the market on progress as appropriate."

Investor briefing

Sara Barrington, Chief Executive Officer, and David Anderson, Chief Financial Officer, will provide a live presentation relating to the interim results via the Investor Meet Company platform on Tuesday 16 July at 4.30pm BST. This presentation is open to all existing and potential shareholders. Questions can be submitted at any time during the live presentation. Investors can sign up to Investor Meet Company for free and add to meet VERICI DX PLC via:

https://www.investormeetcompany.com/verici-dx-plc/register-investor

Investors who already follow Verici Dx on the Investor Meet Company platform will automatically be invited.

A copy of the Company's interim results report will shortly be made available on the Company's website.

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Singer Capital Markets (Nominated Adviser & Broker)

Phil Davies / Sam Butcher / Jalini Kalaravy

About Verici Dx plc www.vericidx.com

Verici Dx is a developer of a complementary suite of leading-edge tests forming a kidney transplant platform for personalised patient and organ response risk to assist clinicians in medical management for improved patient outcomes. The underlying technology is based upon artificial intelligence assisted transcriptomic analysis to provide RNA signatures focused upon the immune response and other biological pathway signals critical for transplant prognosis of risk of injury, rejection and graft failure from pre-transplant to late stage. The Company also has a mission to accelerate the pace of innovation by research using the fully characterised data from the underlying technology and in collaboration with medical device, biopharmaceutical and data science partners.

The foundational research was driven by a deep understanding of cell-mediated immunity and is enabled by access to expertly curated collaborative studies in highly informative cohorts in kidney transplant.

Chief Executive Officer's Report

I am pleased to report that the momentum gained in 2023 continued throughout the first half of 2024. We successfully achieved all the key milestones expected during the period under the Thermo Agreement. Concurrently, we have advanced multiple other projects and initiatives, demonstrating delivery across the full breadth of our strategy.

Continued execution on our commercial pathway

Direct Revenues

While the commercial rollout of Tutivia[™] encountered some initial short-term delays during 2023, due in part to clinical centres assessing the broader market implications of certain CMS announcements. Recent engagement with centres indicates increased clarity on these issues and is reflected in the rapid expansion of adopting centres in 1H 2024. Tutivia[™] is now offered in fifteen leading transplant centres across the United States and, with our more recently expanded sales team, we continue to work with other leading US transplant centres to support the adoption and integration of Tutivia into their clinical pathways to encourage consistent and recurring utilisation.

We presented new performance data on Tutivia[™] in the setting of delayed graft function ("DGF") and generated interest from practitioners at the June American Transplant Congress ("ATC") meeting. DGF is a condition that can lead to a higher risk of rejection and identifying which patients are likely to experience rejection in this population is a currently unmet need in transplantation. This has been reflected in part in the increase of adoption of Tutivia[™] in the period.

As previously announced, the national payment rate of \$2,650 per test for our two lead tests became effective from 1 January 2024. Having this rate published by CMS was an important step towards securing reimbursement for testing of patients covered by Medicare insurance.

We submitted the Technical Assessment (TA) file for Tutivia[™] in Q1 2024. We are now actively engaged in the next stage in this process, addressing questions raised by the initial review. Revenue recognition from Tutivia[™] remains dependent upon securing the LCD for Medicare under this pathwayand we expect to have a determination by the end of 2024. The Company will be able to apply for retrospective reimbursement on testing to date and during the assessment period once the Local Coverage Determination (LCD) is granted.

Licensing Revenues

In June, the Company successfully completed the transfer and all transfer-related activities for the pretransplant prognostic testing technology in accordance with the terms of the Thermo Agreement. This achievement now enables Thermo Fisher to use the technology to develop a Laboratory Developed Test ("LDT") using its own labs. We will continue to provide support as required to Thermo Fisher as they move towards a full commercial launch. As a reminder, under the terms of the agreement, the Company will receive future milestone payments one being a commercial milestone to be met by Thermo Fisher, and royalties on the tests sold going forward.

Other products

With the exclusive license over the deceased donor version of Clarava[™] granted to Thermo Fisher, we remain interested in the potential to develop a living donor version of Clarava[™]. To this end, the Company is exploring multiple approaches to expanding its testing cohort to maximize cost and time efficiencies.

Turning to our third product, Protega[™], we have now completed the 12-month visits as part of the clinical validation study assessing long-term outcomes for kidney transplant patients. We remain on track and initial data from this part of the study is expected to be available in H1 2025. As stated at the time of our recent fundraising, the cohort has been expanded to increase the robustness of results and improve commercialisation over the longer term. The study will therefore continue to follow-up at the 24-month stage to provide additional data and further potential validation on longer-term outcomes.

Services Business

Collectively, these activities demonstrate the clinical validity of the underlying technology, research assets and expertise in RNA signatures. The Company remains alert to the potential opportunities in its technology, expertise and approach in other disease areas.

Consistent delivery of operational milestones

In addition to the above progress across our lead products, the Company achieved a number of key operational milestones during the period.

Foremost amongst these was the successful transfer of all data relating to a portion of the Company's urine samples to Thermo Fisher. This completed a key element of the Thermo Agreement and demonstrates the additional value in the Company's Services Business through its data and sample assets for research.

As previously announced, during 2023 we solidified our commercial position by progressing our laboratory registration status to CLIA Certificate of Compliance by the Centers for Medicare & Medicaid ("CMS"), meaning that the Company is currently fully accredited in all except one state. We have now submitted for review the application for the final US state, New York, which involves several additional stages prior to accreditation compared to the process in the other states.

In May 2024, we were delighted to launcha new interactive patient-focused educational tool, the Patient Journey, which provides a detailed overview of all stages of the kidney transplant journey. This aligns with

the Company's goal to enhance patient care and support by ensuring that patients and caregivers have access to the latest information and best practices for kidney transplant care.

We continue to add to our existing portfolio of quality assurance awards and recognition as we gained accreditation from the internationally recognised College of American Pathology (CAP) for the testing laboratory in Franklin, TN, following the completion of an on-site audit. No deficiencies, findings, or recommendations were identified, and this accomplishment affirms our commitment to operating at the highest standards that healthcare providers, patients, and regulatory bodies expect. With our testing laboratory already CLIA certified, we voluntarily sought this further accreditation as part of our on-going commitment to maintaining best-in-class quality systems.

Collaborations remain an integral part of our strategy. This can be evidenced through the growing international recognition and reach in our newest collaboration with The Westmead Institute for Medical Research based in Sydney, Australia, on a newly awarded, 4-year federal research grant. This will expand our international reach. We are currently engaged in a number of other opportunities for collaborations going forward.

Management and staff

During the period, we hired five additional members of staff in our bioinformatics and commercial teams in line with our growth plans articulated at the time of the fundraising in February 2024, such that as of 30 June 2024 we have a team of 19 in total.

Financials

We ended the period with a cash balance as of 30 June 2024 of \$7.0m (31 December 2023: \$2.6m). This balance reflects the net raise of \$7.5m from the February 2024 share issue of 72,222,222 shares, and the further \$1.3m received during the period under our agreement with Thermo Fisher. To date, we have received a total \$2.8m of the \$5.0m payments expected in the first 12 months of the agreement and are on track for the remainder.

In the period we recognised revenue of \$3.3m. Our ability to recognise revenues from Tutivia[™] sales in the current year is dependent upon the successful award of the Local Coverage Determination from Medicare, expected later this year.

Our largest item of expenditure remains employment costs, being \$1.9m (H1 2023: \$1.8m). We began the year with 14 members of staff and ended the period with 19, having added to our bioinformatics and commercial teams in the period. As we have passed the peak of our clinical trial costs, our second highest spend on research and development has reduced, with the cost in the period of \$1.0m (H1 2023: \$1.6m).

Despite the challenging global financing environment, we significantly strengthened our financial position through both the Thermo Agreement announced in November 2023, and the early 2024 equity fundraise which raised a total of £6.5m (\$8.2m) in gross proceeds (£6.0 m/ \$7.5m net) through the issue of 72,222,222 new ordinary shares. We are grateful to existing shareholders for their continued support and delighted to welcome those new to the register. Based on our balance sheet at 30 June 2024, together with our continuing assumptions relating to the timing and/or quantum of the additional milestone payments under the Thermo Agreement, the ongoing rollout of Tutivia[™] as well as other licensing revenues and research collaborations, our cash runway extends into 2026

Business Model Overview

The Company is focused upon three distinct revenue streams: licensing opportunities, direct sales, and promotion of a services business line which recognises the tangible assets of samples and data as well as the expertise of the team in this complex area of product development and is applicable in multiple disease areas.

Licensing is a capital-efficient approach to clinical adoption for the multiple products within the portfolio and the Company has already demonstrated its ability to complete significant milestones on time with a major collaborator. The Company will continue to assess future opportunities on a deal-by-deal basis to maximize shareholder return.

The direct sales approach is appropriate for our lead product, Tutivia^{IM}, where the Company has chosen to seek coverage under the Local Coverage Determination issued by MolDx for Medicare, as this pathway offers

a fuller and more accelerated reimbursement than other pathways. Nationally, 65% of transplant patients are covered by Medicare and Medicaid. Part of the process of obtaining this LCD is the submission of a Technical Assessment ("TA") file which was completed in Q1 2024. A coverage determination for Medicare reimbursement is now expected by the end of 2024, but it is important to note that there is a route for retrospective reimbursement to be applied on tests ordered during the LCD approval process.

Underlying our mainstream product development in kidney transplant, the Company has developed an expertise in RNA sequencing and RNA signature development within a regulatory environment that is now monitored by the FDA. This, coupled with the physical samples collected in multiple biological materials and the wide applicability of the data generated both for diagnostic and therapeutic collaborations, has now coalesced into an additional Services Business line.

Outlook

Through the ongoing agreement with Thermo Fisher and with the focus from our recently enlarged sales team on both direct sales of Tutivia [™] and the Services Business, we are positive regarding the outlook for further attainment of our objectives and value creation across all our business lines. In addition, the Company has a longer-term product development in the pipeline plus additional optionality from the potential to expand into other related areas.

On behalf of the Company, I would like to thank our shareholders for their ongoing support and look forward to providing further updates in due course.

Sara Barrington

Chief Executive Officer

15 July 2024

Consolidated condensed statement of profit or loss and other comprehensive income for the six months ended 30 June 2024

	Note	Six months to 30 June 2024 US\$'000 Unaudited	Six months to 30 June 2023 US\$'000 Unaudited	Year to 31 December 2023 US\$'000 Audited
Revenue Cost of sales	5	3,339 -	19 (3)	1,013
		3,339	16	1,013
Administrative expenses Depreciation and amortisation Share-based payments	6 6 6	(4,368) (388) (36)	(4,825) (472) (99)	(8,598) (829) (453)
Loss from operations		(1,453)	(5,380)	(8,867)
Finance income Finance expense		118 (13)	122 (15)	162 (29)
Loss before tax		(1,348)	(5,273)	(8,734)
Tax expense		-	-	-
Loss from continuing operations Other comprehensive income:		(1,348)	(5,273)	(8,734)
Exchange gains / (losses) arising on translation of foreign operations		102	353	330

Loss and total comprehensive income attributable to the owners of the Company		(1,246)	(4,920)	(8,406)
Earnings per share attributable to the ordinary equity holders of the parent				
Loss per share Basic and diluted (US\$ cents)	7	(\$0.6)	(3.1)	(5.1)

The results reflected above relate to continuing operations.

Consolidated statement of financial position as at 30 June 2024

Assets	Note	30 June 2024 US\$'000 Unaudited	30 June 2023 US\$'000 Unaudited	31 December 2023 US\$'000 Audited
Current assets				
Trade and other receivables	8	1,934	426	1,344
Cash and cash equivalents		7,015	5,249	2,645
		8,949	5,675	3,989
Non-current assets				
Property, plant and equipment		1,073	1,641	1,363
Intangible assets		2,084	2,037	2,091
		3,157	3,678	3,454
Total assets		12,106	9,353	7,443
Liabilities				
Current liabilities	_	(4)	(2.24)	(0.0.5)
Trade and other payables Lease liabilities	9 10	(1,787)	(2,044)	(3,345)
Non-current liabilities	10	(184)	(159)	(163)
Lease liabilities	10	(274)	(462)	(377)
NET ASSETS		9,861	6,688	3,558
NET ASSETS		5,001	0,000	3,336
Issued capital and reserves attributable to owners of the parent				
Share capital		310	219	219
Share premium reserve		40,368	32,946	32,946
Share-based payments reserve		4,342	3,952	4,306
Foreign exchange reserve		(605)	(684)	(707)
Retained earnings		(34,554)	(29,745)	(33,206)
TOTAL EQUITY		9,861	6,688	3,558

	Six months to 30 June 2024 US\$'000 Unaudited	Six months to 30 June 2023 US\$'000 Unaudited	Year to 31 December 2023 US\$'000 Audited
Cash flows from operating activities Loss for the period	(1,348)	(5,273)	(8,734)
Adjustments for: Depreciation and amortisation	388	472	829
Finance income	(118)	(122)	(162)
Finance expense Share-based payment expense	13 36	15 99	29 453
	(1,029)	(4,809)	(7,585)
(Increase) / decrease in trade and other receivables	(590)	96	(824)
Increase / (decrease) in trade and other payables Income taxes paid	(1,558) - -	(53) - 	1,249
Net cash outflow from operating activities	(3,177)	(4,766)	(7,160)
Cash flows from investing activities			
Purchases of property, plant and equipment Purchase of intangibles	(14) (81)	(23) (83)	(23) (208)
Net cash used in investing activities	(95)	(106)	(231)
Cash flows from financing activities			
Issue of ordinary shares	8,196	-	-
Expenses of share issue	(683)	-	-
Interest received	118	122	162
Interest paid Repayment of lease liabilities	(13) (82)	(15) (79)	(29) (160)
Net cash from / (used in) financing activities	7,536	28	(27)
Net increase / (decrease) in cash and cash equivalents	4,264	(4,844)	(7,418)
Cash and cash equivalents at beginning of period Exchange movement on cash and cash equivalents	2,645 106	9,805 288	9,805 258
Cash and cash equivalents at end of period	7,015	5,249	2,645

	Share capital US\$'000	Share premium US\$'000	Share-based payment reserve US\$'000	Foreign exchange reserve US\$'000	Retained earnings US\$'000	attr t h
1 January 2023	219	32,946	3,853	(1,037)	(24,472)	
Comprehensive income for the period Loss for the period Other comprehensive income Contributions by and distributions to	- -	-	-	- 353	(5,273) -	
owners Share based payments charge	-	-	99	-	-	
At 30 June 2023 - unaudited	219	32,946	3,952	(684)	(29,745)	_
At 1 July 2023	219	32,946	3,952	(684)	(29,745)	
Comprehensive income Loss for the period Other comprehensive income Contributions by and distributions to	-	-	-	(23)	(3,461)	
owners Share-based payment			354			_
At 31 December 2023 - audited	219	32,946	4,306	(707)	(33,206)	

Consolidated statement of changes in equity for the six months ended 30 June 2024

	Share capital US\$'000	Share premium US\$'000	Share-based payment reserve US\$'000	Foreign exchange reserve US\$'000	Retained earnings US\$'000	attri to ho
1 January 2024	219	32,946	4,306	(707)	(33,206)	
Comprehensive income for the period Loss for the period Other comprehensive income Contributions by and distributions	-	-	<u>.</u>	- 102	(1,348)	
to owners Issue of share capital Costs of share issue	91 -	8,105 (683)		- -	-	
Share-based payment			36			
At 30 June 2024 - unaudited	310	40,368	4,342	(605)	(34,554)	_

1 General information

The principal activity of Verici Dx plc (the "Company") is the development of prognostic and diagnostic tests for kidney transplant patients.

The Company is a public limited company incorporated in England and Wales and domiciled in the UK. The address of the registered office is Avon House, 19 Stanwell Road, Penarth, Cardiff CF64 2EZ and the company number is 12567827.

The Company was incorporated as Verici Dx Limited on 22 April 2020 as a private company and on 9 September 2020 the Company was re-registered as a public company and changed its name to Verici Dx plc.

2 Summary of significant accounting policies

The principal accounting policies adopted in the preparation of the financial information of the Company, which have been applied consistently to the period presented, are set out below:

Basis of preparation

The accounting policies adopted in the preparation of the interim consolidated financial information are consistent with those of the preparation of the Group's annual consolidated financial statements for the year ended 31 December 2023. No new IFRS standards, amendments or interpretations became effective in the six months to 30 June 2024.

Revenue

Revenue is recognised in accordance with the requirements of IFRS 15 'Revenue from Contracts with Customers'. The Company recognises revenue to depict the transfer of promised goods and services to customers in an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods and services.

Testing revenues

Diagnostic test revenues are recognised in the amount expected to be received in exchange for diagnostic tests when the diagnostic tests are delivered. The Company conducts diagnostic tests and delivers the completed test results to the prescribing physician or patient, as applicable.

The fees for diagnostic tests are billed either to a third party such as Medicare, medical facilities, commercial insurance payers, or to the patient.

The Company estimates the transaction price, which is the amount of consideration it expects to be entitled to receive in exchange for providing services based on its historical collection experience, and the probability of being paid at the time of delivering the test result.

Other revenues

Where a right of use license is entered into revenue is recognised when the license is granted, unless there are conditions attached. Where conditions are attached the revenue will only be recognised when all the performance obligations have been satisfied.

Where a sales-based license is entered into which is conditional on future performance criteria, revenue is recognised once the performance obligation to which some or all of the sales-based criteria has been allocated has been satisfied.

Statement of compliance

this internit consolidated inialicial information for the six months ended so rule 2024 has been prepared in

accordance with IAS 34, 'Interim financial reporting' and the AIM Rules for Companies. This interim consolidated financial information is not the Group's statutory financial statements and should be read in conjunction with the annual financial statements for the year ended 31 December 2023, which have been prepared in accordance with UK adopted International Accounting Standards (UK IFRS) and have been delivered to the Registrar of Companies. The auditors have reported on those accounts; their report was unqualified and did not contain statements under section 498(2) or (3) of the Companies Act 2006.

The interim consolidated financial information for the six months ended 30 June 2024 is unaudited. In the opinion of the Directors, the interim consolidated financial information presents fairly the financial position, and results from operations and cash flows for the period. Comparative numbers for the six months ended 30 June 2023 are unaudited.

Measurement convention

The financial information has been prepared under the historical cost convention. Historical cost is generally based on the fair value of the consideration given in exchange for assets.

The preparation of the financial information in compliance with IFRS requires the use of certain critical accounting estimates and management judgements in applying the accounting policies. The significant estimates and judgements that have been made and their effect is disclosed in note 3.

Basis of consolidation

The consolidated financial statements present the results of the company and its subsidiaries (the "Group") as if they formed a single entity. Intercompany transactions and balances between group companies are therefore eliminated in full.

Taxation

Income tax expense represents the sum of the tax currently payable and deferred tax.

3 Judgements and key sources of estimation uncertainty

The preparation of the Company's historical financial information under IFRS requires the Directors to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities. Estimates and judgements are continually evaluated and are based on historical experience and other factors including expectations of future events that are believed to be reasonable under the circumstances. Actual results may differ from these estimates.

The Directors consider that the following estimates and judgements are likely to have the most significant effect on the amounts recognised in the financial information.

Carrying value of intangible assets, property, plant and equipment

In determining whether there are indicators of impairment of the Company's intangible assets, the Directors take into consideration various factors including the economic viability and expected future financial performance of the asset and when it relates to the intangible assets arising on a business combination, the expected future performance of the business acquired.

Going concern

The preparation of cash flow forecasts for the Group requires estimates to be made of the quantum and timing of cash receipts from future commercial revenues and the timing of future expenditure, all of which

4 Segment information

The Group has one division being the development of prognostic and diagnostic tests for kidney transplant patients. The directors consider that all activities relate to this segment. All the non-current assets of the Group are located in, or primarily relate to, the USA.

5 Revenue

Revenue	Six months to 30 June 2024 US\$'000 Unaudited	Six months to 30 June 2023 US\$'000 Unaudited	Year to 31 December 2023 US\$'000 Audited
Product services License revenue	2 3,337 ———	19 -	1,013
	3,339	19	1,013

6 Expenses by nature

	Six months to 30 June 2024 US\$'000 Unaudited	Six months to 30 June 2023 US\$'000 Unaudited	Year to 31 December 2023 US\$'000 Audited
Employee benefit expenses	1,944	1,863	3,813
Depreciation of property, plant and equipment	303	394	673
Amortisation of intangible assets	85	78	156
Research and development costs	1,002	1,641	2,429
Licenses and milestones	250	50	50
Professional costs	406	490	948
Share-based payment expense for non-employees	3	41	248
Foreign exchange losses / (gains)	28	296	272
Other costs	771	543	1,291
	4,792	5,396	9,880

7 Earnings per share

Numerator	Six months to 30 June 2024 US\$ Unaudited	Six months to 30 June 2023 US\$ Unaudited	Year to 31 December 2023 US\$ Audited
Loss for the period used in basic EPS	(1,348,528)	(5,272,803)	(8,734,093)
Denominator			
Weighted average number of ordinary shares used in basic EPS	222,590,577	170,319,245	170,319,245
Resulting loss per share - US\$ cents	(0.6)	(3.1)	(5.1)

The Company has one category of dilutive potential ordinary share, being share options. The potential shares were not dilutive in the period as the Group made a loss per share in line with IAS 33.

8 Trade and other receivables

	30 June 2024 US\$'000 Unaudited	30 June 2023 US\$'000 Unaudited	31 December 2023 US\$'000 Audited
Accounts receivable	1,500	19	1,013
Prepayments	386	288	244
Other debtors	48	119	87
	1,934	426	1,344

9 Trade and other payables

. ,	30 June 2024 US\$'000 Unaudited	30 June 2023 US\$'000 Unaudited	31 December 2023 US\$'000 Audited
Trade payables	661	1,034	475
Other creditors	7	-	48
Deferred income	-	-	1,500
Accruals	1,119	1,010	1,322
Total trade and other payables	1,787	2,044	3,345

The carrying value of trade and other payables classified as financial liabilities measured at amortised cost approximates fair value.

10 Lease liabilities

Group	Land and buildings US\$'000	Plant and machinery US\$'000	Total US\$'000
At 1 January 2023	461	239	700
Interest expense	7	8	15
Repayments	(47)	(47)	(94)
At 30 June 2023 - unaudited	421	200	621
Repayments	(49)	(46)	(95)
Interest expense	7	7 	
At 31 December 2023 - audited	379	161	540
At 1 January 2024	379	161	540
Interest expense	7	6	13
Repayments	(48)	(47)	(95)
At 30 June 2024 - unaudited	338	120	458
At 30 June 2024 - unaudited	338		4

The Company operates from one office which is rented under a lease agreement ending on 1 November 2027 under which rent is payable monthly.

11 Share-based payment

On 28 October 2020, the Board adopted the Share Option Plan to incentivise certain of the Group's employees and Directors. The Share Option Plan provides for the grant of both EMI Options and non-tax favoured options. Options granted under the Share Option Plan are subject to exercise conditions as summarised below.

The Share Option Plan has a non-employee sub-plan for the grant of Options to the Company's advisors, consultants, non-executive directors, and entities providing, through an individual, such advisory, consultancy, or office holder services. In addition there is a US sub-plan for the grant of Options to eligible participants in the Share Option Plan and the Non-Employee Sub-Plan who are US residents and US taxpayers.

With the exception of options over 10,631,086 shares, which vested immediately on grant, the options vest equally over twelve quarters from the grant date. If options remain unexercised after the date one day before the tenth anniversary of grant such options expire. The Options are subject to exercise conditions such that they shall, subject to certain exceptions, vest in equal quarterly instalments over the three years immediately following the date of grant, which vesting shall accelerate in full in the event of a change of control of the Company.

	Weighted average exercise	
	price (p)	Number
Outstanding at 1 January 2023 Granted during the period		6,378,066 250,000
Cancelled during the period		(300,000)
Outstanding at 30 June 2023 - unaudited	25.56	6,328,066
Granted during the period		100,000
Outstanding at 31 December 2023 - audited	23.86	6,428,066
Granted during the period Cancelled during the period		1,690,000 (100,000)
Outstanding at 30 June 2023 - unaudited	13.90	8,018,066

The Group recognised total expenses of \$36,000 (six months to 30 June 2023 - \$99,000) as administrative expenses relating to equity-settled share-based payment transactions during the period to 30 June 2024.

12 Events after the reporting date

There have been no events subsequent to the period end that require disclosure in these financial statements.

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