



29 September 2023

Verici Dx plc
(“Verici Dx” or the “Company”)

Half-year report

Continuing to build the foundations for commercial success.

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 2023.

Operational highlights (including post-period end)

- Initial revenues following the commercial launch of our first product, Tutivia™, the Company’s post-transplant prognostic test for the assessment of risk of acute kidney rejection.
 - Full year revenues from Tutivia™ are likely to be less than expected although the Company has recently doubled the number of US transplant centers as early adopters of the test.
- The impact of lower Tutivia revenues is expected to be offset by higher than expected research-related revenues so that that cash runway expectations to mid-2024 are unchanged at this time.
- Successful clinical validation of our second product, Clarava™, the Company’s pre-transplant prognostic test, demonstrating a statistically significant result and capability to stratify patients based on their likely immune response to a transplanted kidney, informing a clear, actionable response for clinicians.
 - Clarava™ is on track for initial US commercial use by the end of 2023 under prospective real-world evidence studies.
- Completed patient enrolment for the multi-centre clinical validation study of the Company’s third product, Protega™, assessing long-term outcomes for kidney transplant patients.
- Received preliminary gapfill median rate of \$2,650 proposed for both Clarava™ and Tutivia™ by the Centers for Medicare & Medicaid Services (“CMS”). These rates are due to be finalised later this year and represent a substantial uplift from the Company’s initial assumption for modelling purposes.
- Two key patents granted in the United States underpinning Verici Dx’s products.
- Achieved CLIA Certificate of Compliance for clinical laboratory in Nashville, TN, USA, a key requirement to obtaining insurance reimbursement coverage under Medicare and allowing for expanded commercial launch of Tutivia™ in 49 out of 50 US states to date.
- Submitted final responses to comments for our peer-reviewed publication on the Tutivia clinical validation. Final publication dependent on publishers.
- Initiated studies in our databank to facilitate product development and further research collaborations.
- Obtained Medicaid approvals in 15 States and a further 12 States pending.

Outstanding clinician feedback on Tutivia™

We have been delighted with the feedback on Tutivia™ following its commercial launch at the start of 2023.

“In the first few months post-transplant there are many rejection events and yet in my opinion we have not really had a biomarker that can assist at this critical time. Tutivia™ is able to give the clinician reliable test results as soon as the first week post-transplant and so is an early biomarker test which addresses this critical need.”

Dr Nicolae Leca Professor, Medical Director, Kidney and Pancreas Transplant - University of Washington

Financial highlights

- Adjusted EBITDA loss of \$4.8m (six months to 30 June 2022: loss of \$5.0m), excluding share-based payments.
- \$5.3m cash balance as at 30 June 2023 (31 December 2022: \$9.8m).
- Net cash outflow from operating activities in the six months to 30 June 2023 was \$4.7m (six months to 30 June 2022: \$5.0m) with investing activities consuming a further \$0.1m (six months to 30 June 2022: \$0.7m).

The full year revenues are expected to be lower than originally projected from Tutivia but offset by higher than expected revenues from research collaborations. Revenues and containment of total costs mean that cash runway expectations to mid-2024 are unchanged at this time.

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

"I am proud of the progress we have made in the first six months of this year. The clinician response to our first product, Tutivia™, following its commercial launch at the start of the year clearly demonstrates how much they value the key benefits and recognise the strong differentiating features. We are also excited to have announced a second successful product, Clarava™, following the recently completed clinical validation study showing excellent results. This allows us to prepare for its initial launch in due course. We also completed enrolment for the validation study on our third product, Protega™. Whilst this product has a much longer time frame, it completes the end-to-end testing for the portfolio as we look ahead.

"Although the timing effects on early adoption are frustrating, we have been able to make savings in other areas and are focused on research collaborations to help build a solid platform for future growth. At the same time, we are continuing to deliver on our strategy of transforming kidney transplant patient outcomes, as we move further into commercialisation."

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 Thursday October 5 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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Verici Dx

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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 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

Progress in the first six months of 2023 saw the Company transition to a fully commercial-stage business following the initial launch of Tutivia™. Following the successful clinical validation of our pre-transplant test, Clarava™, we are also now poised for the commercialization of our second product starting with prospective real-world evidence studies. Turning to our third product, Protega™, we completed enrolment for the validation trial and expect to be fully completed with the 24-month end point in Q1 2025, although the Company expects to review performance on an interim timepoint. Together, these demonstrate the clinical validity of the underlying technology in RNA signatures for kidney transplant patients, providing early predictive tests to cover the full transplant lifecycle, from pre-transplant to late-stage, enabling clinicians to make more informed treatment decisions.

In addition, the Company achieved a number of key operational milestones during the period, including receiving our CLIA Certificate of Compliance now covering 49 states, including California representing 10% of US transplants by volume, and the strengthening of our intellectual property portfolio.

Executing on commercial pathway

Tutivia™ commercially launched in January 2023, following an initial pilot launch in December 2022. We continue to work with leading US transplant centers to support the adoption and integration of Tutivia™ into their clinical pathways to encourage consistent and recurring utilisation. This provides valuable information for us to make Tutivia™ as simple as possible for clinicians to use and interpret, which in turn will help support the accelerated roll out of the test to other major transplant centers across the US. The Company previously highlighted the short-term confusion by clinical centers as they assessed the announcements made by CMS and this led to a slow down in bringing in centers into the early adopter program in Q2 and early Q3. Based on our current interactions with centers this appears to have been resolved and we are pleased to report a recent doubling of adopting centers in the later part of Q3. Timing of the submission of the application under the Local Coverage Determination is predicated upon the acceptance of the clinical validation publication for Tutivia and having recently responded to peer reviewer questions we are hoping that this is now imminent.

We also announced the successful validation results from our multi-centre clinical validation study for Clarava™. The study, which included a broad and diverse group of patients preparing to receive a kidney transplant across 13 centers, demonstrated a statistically significant result, identifying patients that are at increased risk for a kidney rejection event in the critical first 60 to 90 days post-transplant after receiving a kidney from a deceased donor (c.65,000 patients eligible per year). Study data analysis of the clinical performance of Clarava™ determined that patients of high risk based on their test result were approximately six times more likely to have a rejection than those of low risk. This demonstrated Clarava™ to be capable of informing a clear, actionable response from clinicians. The Company remains on track to commence the initial US launch of Clarava™ before the end of 2023 through prospective real-world evidence studies.

Enrolment into the longer duration Protega™ validation study was finalised in the first quarter of 2023. Protega™ is the third product to emerge from our platform of personalised, predictive RNA signature tests, completing our offering for end-to-end kidney transplant testing, from pre-transplant to long-term damage. We expect that the final validation point will be completed after follow-up at the 24-month point for the last patient tested, which is expected to be in Q1 2025. The Company expects to be able to review interim data before this point.

Operational milestones

During the period we successfully progressed our laboratory registration status to CLIA Certificate of Compliance by the Centers for Medicare & Medicaid ("CMS"), allowing our commercial clinical operations to process samples from 45 US states, following an inspection by CMS of our clinical laboratory in Franklin, Tennessee. In July, we received authorisation from a further four states, including California, meaning Verici Dx is now fully accredited in 49 states, and is currently working on reaching accreditation in New York state, solidifying our commercial positioning.

This also represents a major milestone towards US Medicare reimbursement, for which we are preparing our submission, a key milestone to driving adoption with Medicare covering 63.9 million US patients. We have also now received a preliminary Medicare price recommendation of \$2,650 for both Clarava™ and Tutivia which represents an increase to the price used in previous forecasts. The price will be finalised later this year following a period of public

consultation. This is a key milestone in our commercial strategy and advances us closer to achieving coverage under Medicare.

Additionally, registration for Medicaid has been approved in 15 states, as well as with BlueCross Blue Shield of Tennessee, the largest health benefit plan company in the state, with a further 12 states pending. Together, Medicaid and Medicare patients account for 65% of all transplant recipients across the US¹.

The Company was also granted two key patents in the United States that support and protect the Company's core technologies in RNA signature biomarker tests used for assessment of the prognostic risk pre-transplant (Clarava™) and post-transplant (Tutivia™) of acute kidney transplant rejection. The protection of the Company's intellectual property is fundamental to our strategy of amassing full transcriptomic data from the biological systems and interactions associated with transplant rejection and, over the longer term, informing transplant analysis in other organs and in the broader field of immune-mediated diseases.

Management and staff

During the period, we hired one additional member of staff to assist with the research asset, whilst two employees exited. As of 30 June 2023, the Company had 14 employees. As previously noted, the commercial team is sufficient for the early adopter program but will need to be increased at the appropriate time to drive more widespread adoption.

Financials

Cash balance as of 30 June 2023 was \$5.3m (30 June 2022: \$15.7m; 31 December 2022: \$9.8m), the prior period augmented by the net proceeds from the issue of 28,571,429 new ordinary shares in March 2022 of \$12.5m. Net cash outflow in the six months to 30 June 2023 from operating activities was \$4.7m (six months to 30 June 2022: \$5.0m) with investing activities consuming a further \$0.1m (six months to 30 June 2022: \$0.7m) and unrealised foreign exchange gain of \$0.3m (six months to 30 June 2022: loss of \$1.5m).

Our largest item of expenditure is employment costs, being \$1.8m (six months to 30 June 2022: \$1.3m), reflecting the additions to the team on the commercial and data asset side. We began the year with 15 members of staff and end the period with 14 members of staff. In the six months to 30 June 2022 our average team size was 10. 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 \$1.6m (six months to 30 June 2022 - \$2.3m).

Updated Trading Position

Our expectation for a cash runway extending to mid-2024 was predicated on our revenue assumptions regarding the number of test results delivered and the subsequent reimbursement of those tests. In addition, the number of test results delivered was based on our assumptions about the number of US transplant centers ordering the test.

Modest revenue of \$19k for the first half reflected the early use of Tutivia™ in a small number of centers in the early adoption program. As of the date of this report, we are expanding our centers in the program and are already seeing an increase in number of tests ordered both from new centers and from recurring ordering from established clinicians. We are pleased to see this increase in orders coming through, however, it is still lower than our original assumptions. This reflects a number of factors:

- In order to focus on a high-quality customer experience whilst carefully managing costs, we made the commercial decision to operate with a very small sales team of two persons to cover business development and clinical communications. A larger team will be needed to support further growth beyond the early adopting centers. Going forward, we can consider a distribution partner or a direct sales force of around 10 to 12 individuals to facilitate more ambitious targets over time. This size of direct sales team would remain modest relative to industry averages.
- Whilst we believe the impact of some of the recent CMS clarifications² is favourable for Verici Dx over the medium-term, the need to understand the impacts to testing protocols across the market has, on occasion, constrained our ability to initiate or progress conversations. Towards the end of Q3 this short-term impact appears to have lessened

- We have also encountered some logistical issues in sample collection affecting early adoption, which we have now resolved.

Nationally, 65% of transplant patients are covered by Medicare and Medicaid. For the Company to be able to be fully reimbursed by Medicare we need the award of a Local Coverage Determination (“LCD”). Part of the process of obtaining this LCD is the submission of a Technical Assessment which, among other matters, includes a peer reviewed publication of our clinical validation study for Tutivia™. The publication process has taken longer than originally anticipated, due to extraneous factors, thus delaying our ability to submit the Technical Assessment and apply for the award of the LCD. This directly impacts on the time taken for tests to be reimbursed. Our original expectation was reimbursement would occur in Q4 of 2023. This is now expected in Q1 of 2024 but it is important to note that there is a route for retrospective reimbursement to be applied on tests ordered in the year before approval of the LCD is obtained.

There has been demonstrable progress of our two lead products and with a third product in the pipeline, underpinned by the strong platform and opportunities for revenues from the research asset through research collaborations, and despite currently operating with a very small sales team, the Company has established a solid commercial platform for growth, with a rising revenue stream.

The combination of slower initial traction with US transplant centers and the delayed reimbursement profile would ordinarily have shortened our expected cash runway to mid-2024, but this reduction is expected to be offset by research revenues and runway guidance is therefore unchanged.

Outlook

Looking ahead, we are focussed on accelerating the commercial rollout of Tutivia™ and will look to enrol more leading transplant centers in the US to begin using the test. Concurrently, we remain on track to commence the initial US commercial launch of Clarava™ before the end of the year, which will support the utility assessments to demonstrate the real-world clinical value of the test.

We expect to secure both Medicare and private payor pricing and coverage for Tutivia™ this year, which will be a key catalyst to enabling more widespread adoption as well as revenue generation and cash collection. Following our receipt of the CLIA Certificate of Compliance covering 49 states, we will also look to receive full accreditation in New York, which has its own compliance requirements. Given Clarava™ is a first-in-class pre-transplant test, adoption can be expected to be promoted by the results of prospective real-world evidence on utility for hospital centers.

As previously indicated, there are further research and product development opportunities from the clinical trial samples and data. For example, we will be exploring further samples drawn from living donor transplant recipients to assess Clarava’s™ potential utility in that patient population, in addition to assessing the anticipated combination of using the test in conjunction with Tutivia™, as well as assessing the role of urine-based testing.

Following the publication on Tutivia™ validation results, we are expecting to submit publications for Clarava™ validation, analytical validation and health economics models to aid our commercialisation efforts. We also expect to engage in real-world evidence studies to further support adoption of our products both later this year and into next year.

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

28 September 2023

1. Scientific Registry of Transplant Recipients: OPTN/SRTR 2021 Annual Data Report: Kidney

2. [Article - Billing and Coding: MolDX: Molecular Testing for Solid Organ Allograft Rejection \(A58061\) \(cms.gov\)](#)

**Consolidated condensed statement of profit or loss and other comprehensive income
for the six months ended 30 June 2023**

	Note	Six months to 30 June 2023 US\$'000 Unaudited	Six months to 30 June 2022 US\$'000 Unaudited	Year to 31 December 2022 US\$'000 Audited
Revenue	5	19	-	-
Cost of sales		(3)	-	-
		<u>16</u>	<u>-</u>	<u>-</u>
Administrative expenses	6	(4,825)	(5,004)	(10,497)
Depreciation and amortisation	6	(472)	(275)	(640)
Share-based payments	6	(99)	(195)	(318)
		<u>(5,380)</u>	<u>(5,474)</u>	<u>(11,455)</u>
Loss from operations				
Finance income		122	7	53
Finance expense		(15)	-	(5)
		<u>(5,273)</u>	<u>(5,467)</u>	<u>(11,407)</u>
Loss before tax				
Tax expense		-	-	-
		<u>(5,273)</u>	<u>(5,467)</u>	<u>(11,407)</u>
Loss from continuing operations				
Other comprehensive income:				
Exchange gains / (losses) arising on translation of foreign operations		353	(1,729)	(2,016)
		<u>(4,920)</u>	<u>(7,196)</u>	<u>(13,423)</u>
Loss and total comprehensive income attributable to the owners of the Company				
Earnings per share attributable to the ordinary equity holders of the parent				
Loss per share				
Basic and diluted (US\$ cents)	7	(\$0.031)	(\$0.034)	(\$0.069)
		<u>(\$0.031)</u>	<u>(\$0.034)</u>	<u>(\$0.069)</u>

The results reflected above relate to continuing operations.

**Consolidated statement of financial position
as at 30 June 2023**

	Note	30 June 2023 US\$'000 Unaudited	30 June 2022 US\$'000 Unaudited	31 December 2022 US\$'000 Audited
Assets				
Current assets				
Trade and other receivables	8	426	516	520
Cash and cash equivalents		5,249	15,717	9,805
		<u>5,675</u>	<u>16,233</u>	<u>10,325</u>
Non-current assets				
Property, plant and equipment		1,641	1,310	2,010
Intangible assets		2,037	1,944	1,970
		<u>3,678</u>	<u>3,254</u>	<u>3,980</u>
Total assets		<u>9,353</u>	<u>19,487</u>	<u>14,305</u>
Liabilities				
Current liabilities				
Trade and other payables	9	(2,044)	(1,874)	(2,096)
Lease liabilities	10	(159)	-	(156)
Non-current liabilities				
Lease liabilities	10	(462)	-	(544)
		<u>(2,665)</u>	<u>(1,874)</u>	<u>(2,796)</u>
NET ASSETS		<u>6,688</u>	<u>17,613</u>	<u>11,509</u>
Issued capital and reserves attributable to owners of the parent				
Share capital		219	219	219
Share premium reserve		32,946	32,946	32,946
Share-based payments reserve		3,952	3,730	3,853
Foreign exchange reserve		(684)	(750)	(1,037)
Retained earnings		(29,745)	(18,532)	(24,472)
		<u>6,688</u>	<u>17,613</u>	<u>11,509</u>
TOTAL EQUITY		<u>6,688</u>	<u>17,613</u>	<u>11,509</u>

**Consolidated statement of cash flows
for the six months ended 30 June 2023**

	Six months to 30 June 2023 US\$'000 Unaudited	Six months to 30 June 2022 US\$'000 Unaudited	Year to 31 December 2022 US\$'000 Audited
Cash flows from operating activities			
Loss for the period	(5,273)	(5,467)	(11,407)
<i>Adjustments for:</i>			
Depreciation and amortisation	472	275	640
Finance income	(122)	(7)	(53)
Finance expense	15	-	5
Share-based payment expense	99	195	318
	<u>(4,809)</u>	<u>(5,004)</u>	<u>(10,497)</u>
(Increase) / decrease in trade and other receivables	96	(140)	136
Increase / (decrease) in trade and other payables	(53)	116	293
Income taxes paid	-	-	-
	<u>(4,766)</u>	<u>(5,028)</u>	<u>(10,068)</u>
Cash flows from investing activities			
Purchases of property, plant and equipment	(23)	(561)	(1,040)
Purchase of intangibles	(83)	(161)	(268)
	<u>(106)</u>	<u>(722)</u>	<u>(1,308)</u>
Cash flows from financing activities			
Issue of ordinary shares	-	13,070	13,070
Expenses of share issue	-	(441)	(441)
Interest received	122	7	53
Interest paid	(15)	-	(5)
Repayment of lease liabilities	(79)	-	(3)
	<u>28</u>	<u>12,636</u>	<u>12,674</u>
Net cash from financing activities	28	12,636	12,674
Net increase / (decrease) in cash and cash equivalents	(4,844)	6,886	1,298
Cash and cash equivalents at beginning of period	9,805	10,340	10,340
Exchange movement on cash and cash equivalents	288	(1,509)	(1,833)
	<u>5,249</u>	<u>15,717</u>	<u>9,805</u>
Cash and cash equivalents at end of period	5,249	15,717	9,805

**Consolidated statement of changes in equity
for the six months ended 30 June 2023**

	Share capital US\$'000	Share premium US\$'000	Share-based payment reserve US\$'000	Foreign exchange reserve US\$'000	Retained earnings US\$'000	Total attributable to equity holders of parent US\$'000	Total equity US\$'000
1 January 2022	182	20,354	3,535	979	(13,065)	11,985	11,985
Comprehensive income for the period							
Loss for the period	-	-	-	-	(5,467)	(5,467)	(5,467)
Other comprehensive income	-	-	-	(1,729)	-	(1,729)	(1,729)
Contributions by and distributions to owners							
Issue of share capital	37	13,033	-	-	-	13,070	13,070
Costs of share issue	-	(441)	-	-	-	(441)	(441)
Share based payments charge	-	-	195	-	-	195	195
At 30 June 2022 - unaudited	219	32,946	3,730	(750)	(18,532)	17,613	17,613
At 1 July 2022	219	32,946	3,730	(750)	(18,532)	17,613	17,613
Comprehensive income							
Loss for the period	-	-	-	-	(5,940)	(5,940)	(5,940)
Other comprehensive income	-	-	-	(287)	-	(287)	(287)
Contributions by and distributions to owners							
Share-based payment	-	-	123	-	-	123	123
At 31 December 2022 - audited	219	32,946	3,853	(1,037)	(24,472)	11,509	11,509

**Consolidated statement of changes in equity
for the six months ended 30 June 2023**

	Share capital US\$'000	Share premium US\$'000	Share-based payment reserve US\$'000	Foreign exchange reserve US\$'000	Retained earnings US\$'000	Total attributable to equity holders of parent US\$'000	Total equity US\$'000
1 January 2023	219	32,946	3,853	(1,037)	(24,472)	11,509	11,509
Comprehensive income for the period							
Loss for the period	-	-	-	-	(5,273)	(5,273)	(5,273)
Other comprehensive income	-	-	-	353	-	353	353
Contributions by and distributions to owners							
Share-based payment	-	-	99	-	-	99	99
At 30 June 2023 - unaudited	219	32,946	3,952	(684)	(29,745)	6,688	6,688

Notes forming part of the consolidated financial statements for the six months ended 30 June 2023

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 2022. No new IFRS standards, amendments or interpretations became effective in the six months to 30 June 2023.

Statement of compliance

This interim consolidated financial information for the six months ended 30 June 2023 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 2022, 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 2023 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 2022 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.

The consolidated financial statements incorporate the results of business combinations using the acquisition method. In the statement of financial position, the acquiree's identifiable assets, liabilities and contingent liabilities are initially recognised at their fair values at the acquisition date. The results of acquired operations are included in the consolidated statement of profit or loss and other comprehensive income from the date on which control is obtained. They are deconsolidated from the date on which control ceases.

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 are subject to uncertainty.

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

	Six months to 30 June 2023 US\$'000 Unaudited	Six months to 30 June 2022 US\$'000 Unaudited	Year to 31 December 2022 US\$'000 Audited
Product services	19	-	-

6 Expenses by nature

	Six months to 30 June 2023 US\$'000 Unaudited	Six months to 30 June 2022 US\$'000 Unaudited	Year to 31 December 2022 US\$'000 Audited
Employee benefit expenses	1,863	1,289	2,889
Depreciation of property, plant and equipment	394	203	497
Amortisation of intangible assets	78	72	143
Research and development costs	1,641	2,290	4,832
Licenses and milestones	50	550	550
Professional costs	490	515	1,325
Share-based payment expense for non-employees	41	77	129
Foreign exchange losses / (gains)	296	(510)	36
Costs of share issue	-	90	90
Other costs	543	898	964

7 Earnings per share

	Six months to 30 June 2023 US\$ Unaudited	Six months to 30 June 2022 US\$ Unaudited	Year to 31 December 2022 US\$ Audited
<i>Numerator</i>			
Loss for the period used in basic EPS	(5,272,803)	(5,466,168)	(11,407,527)
<i>Denominator</i>			
Weighted average number of ordinary shares used in basic EPS	170,319,245	158,890,673	164,667,754
Resulting loss per share	(US\$0.031)	(US\$0.034)	(US\$0.069)

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 2023 US\$'000 Unaudited	30 June 2022 US\$'000 Unaudited	31 December 2022 US\$'000 Audited
Accounts receivable	19	-	-
Prepayments	288	324	343
Other debtors	119	192	177
	<hr/>	<hr/>	<hr/>
	426	516	520
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>

9 Trade and other payables

	30 June 2023 US\$'000 Unaudited	30 June 2022 US\$'000 Unaudited	31 December 2021 US\$'000 Audited
Trade payables	1,034	385	960
Other creditors	-	186	-
Accruals	1,010	1,303	1,136
	<hr/>	<hr/>	<hr/>
Total trade and other payables	2,044	1,874	2,096
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>

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 2022 and 30 June 2022	-	-	-
Additions	465	238	703
Interest expense	4	1	5
Repayments	(8)	-	(8)
	<hr/>	<hr/>	<hr/>
At 31 December 2022 - audited	461	239	700
	<hr/>	<hr/>	<hr/>
Repayments	(47)	(47)	(94)
Interest expense	7	8	15
	<hr/>	<hr/>	<hr/>
At 30 June 2023 - unaudited	421	200	621
	<hr/>	<hr/>	<hr/>

The Company acquired an asset under capital lease financing arrangements.

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 2022		4,933,696
Granted during the period		454,370
Cancelled during the period		(120,000)
	<hr/>	<hr/>
Outstanding at 30 June 2022	26.04	5,268,066
Granted during the period		1,110,000
	<hr/>	<hr/>
Outstanding at 31 December 2022 - audited	23.86	6,378,066
Granted during the period		250,000
Cancelled during the period		(300,000)
	<hr/>	<hr/>
Outstanding at 30 June 2023 - unaudited	25.56	6,328,066
	<hr/>	<hr/>

The Group recognised total expenses of \$99,000 (six months to 30 June 2022: \$195,000) as administrative expenses relating to equity-settled share-based payment transactions during the period to 30 June 2023.

12 Events after the reporting date

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