



13 September 2021

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

## Half-year Report

### ***Strong progress made with key milestones towards commercialisation met ahead of schedule***

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 2021.

#### **Strategic and Operational highlights for the period**

- Partnered with five leading US centres to collaborate on clinical validation trial for lead products Clarava™ and Tuteva™.
- Expanded scope of licence agreement with Icahn School of Medicine at Mount Sinai ("Mount Sinai") in January 2021, to include an additional patent filing related to the analysis of gene expression in a blood-based test (liquid biopsy) to predict risk of fibrosis (chronic kidney graft damage) and graft rejection.
- Entered into a Material Transfer Agreement ("MTA") with Mount Sinai to allow access to CTOT-19 (Clinical Trials in Organ Transplant) samples, providing Verici Dx, in combination with the Company's clinical validation study, with a large, well-characterised sample group.

#### **Financial highlights**

- Adjusted EBITDA<sup>1</sup> loss of \$2.52m.
- Cash balance at 30 June 2021 of \$14.5m (31 December 2020: \$17.8m).
  - Strong cash position to expand the Verici Dx platform over time with additional innovative licensing opportunities that complement the existing offering.
  - Engage and build new alliances with patient groups and foundations alike focused on kidney research.

#### **Post-period end**

- Obtained CLIA<sup>2</sup> Certification of Registration for the Company's newly established US clinical laboratory in Tennessee ahead of schedule, authorising the Company to initiate commercial operations as a diagnostic laboratory, a key milestone towards the commercial launch of Clarava™ and Tuteva™.
- Expanded multi-centre clinical validation trial to a total of twelve US and EU sites.
- Completion of patient enrolment to the clinical validation trial for lead products, ahead of schedule.
- Appointment of Lorenzo Gallon, MD, as Non-Executive Director.

**Julian Baines, Non-Executive Chairman, said:** *"The Company has made strong progress over the past six months, with some key milestones reached ahead of schedule as we look to commercialise our innovative organ transplant products.*

*"We initially partnered with five leading US centres in our collaborative, multi-centre observational clinical validation study. We have since expanded to partner with a total of twelve US and European centres for the validation study and completed patient enrolment for Clarava™ and Tuteva™ ahead of schedule. We remain on target for the validation study to be completed by the end of 2021 for lead products, in line with expectations set out at IPO, with the data to be submitted for publication in Q1 2022.*

*"Post-period end, we obtained a CLIA Certification of Registration for our US clinical laboratory in Tennessee. Having a CLIA-certified lab will enable us to launch our two lead products commercially, subject to the successful conclusion of our analytical validation studies. I'd like to thank all of our employees and shareholders for their ongoing hard work and support over the past six months and into the next phases of commercialisation."*

Notes:

1. Earnings before income tax, depreciation and amortisation, adjusted to exclude exceptional items and foreign exchange loss
2. The CLIA (Clinical Laboratory Improvement Amendments) regime is used by the Center for Medicare and Medicaid Services (CMS) to regulate laboratory testing in the US, and requires all clinical laboratories to be certified before they can accept human samples for diagnostic testing

## Investor briefing

Sara Barrington, Chief Executive Officer, and David Anderson, Chief Financial Officer, will provide a live presentation relating to the Final Results via the Investor Meet Company platform on 13 September 2021 at 16:30hrs BST.

The presentation is open to all existing and potential shareholders. Questions can be submitted pre-event via your Investor Meet Company dashboard up until 9.00 a.m. the day before the meeting or 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 plc on the Investor Meet Company platform will automatically be invited.

## Enquiries:

### Verici Dx

Sara Barrington, Chief Executive Officer  
Julian Baines, Non-Executive Chairman

[www.vericidx.com](http://www.vericidx.com)

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## About Verici Dx plc [www.vericidx.com](http://www.vericidx.com)

Verici Dx is an immuno-diagnostics company developing and commercialising tests to understand how a patient will respond and is responding to organ transplant, with an initial focus on kidney transplants. The body's own immune system poses a threat to a successful transplant or graft. Patients' immune systems differ in how they respond to the presence of the transplanted organ. Characterising this response and those of other biological pathways enables the development of RNA signatures for prognostic and diagnostic tests. Our products and solutions are underpinned by extensive scientific research into the recipient's RNA signatures and how that impacts on acute rejection, chronic injury and ultimately failure of the transplant. These RNA signatures may also inform clinicians as to the optimal strategy for immunosuppressive and other therapies for the most successful treatment to ensure graft acceptance with the least amount of side effects.

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.

## Chairman's statement

In the six months ended 30 June 2021, Verici Dx has made significant strides against its strategic goals set out at IPO, with the Company on schedule to meet key milestones.

Our two leading products aim to understand how a patient will and is responding to kidney transplantation:

- **Clarava™**, which is a pre-transplant prognosis for the risk of early acute rejection; and
- **Tuteva™**, a post-transplant diagnostic focused upon acute cellular rejection, including sub-clinical rejection not being diagnosed through the current standard of care of rising serum creatinine levels.

When we were successfully admitted to trading on AIM in November 2020, the c.\$17.6 million net proceeds of our listing were designated primarily to fund the clinical validation studies for Clarava™ and Tuteva™, as well as other bioinformatics and health economic studies. We have made excellent progress on this front, initially partnering with five leading US centres in our collaborative, multi-centre observational clinical validation study. Post-period end, we expanded to a total of twelve US and EU centres, and completed patient enrolment for the study ahead of schedule. This has put us on track to ensure that our lead products are fully tested for validation by the end of 2021, in line with our objectives set out at the time of our IPO in November 2020.

In January 2021, we announced the acceleration of our CLIA laboratory opening and approvals strategy, including the appointment of David Schultenover as Vice President of Quality and Regulatory. This led to us receiving CLIA-certification for our newly established laboratory in Tennessee in July, a major milestone towards the commercial launch of our lead products.

Additionally, we also announced the expansion of the scope of our licence agreement with Mount Sinai in January, to include an additional patent filing related to the analysis of gene expression in a blood-based test (liquid biopsy) to predict risk of fibrosis (chronic kidney graft damage) and rejection of the graft. Assuming successful development, the addition of a product that can predict the risk of long-term graft failure will establish an end-to-end solution for clinicians seeking to understand how a patient will and is responding to organ transplant.

Post-period end, following the sad passing of our colleague, Dr. Barbara Murphy, we appointed Lorenzo Gallon, MD, to the Board of Verici Dx as a Non-executive Director. Lorenzo has extensive experience in nephrology and hypertension and will be an integral advisor helping us accelerate innovation in kidney disease and transplantation, especially on validation of our two lead products, Clarava™ and Tuteva™. He was a collaborator and co-author with Dr. Barbara Murphy in the GoCar study<sup>3</sup>, which was foundational in the development of Verici's products. I would like to take this opportunity to pay tribute to Barbara, who was a passionate and valued friend and member of the Board, who will be missed by all of us at Verici Dx.

On behalf of the Board, I would like to thank our employees, stakeholders and shareholders for their support, and we look forward to providing further updates on progress over the next few quarters as we look to conclude the clinical validation studies for our two leading products.

**Julian Baines**

***Non-Executive Chairman***

13 September 2021

<sup>3</sup> - <https://pubmed.ncbi.nlm.nih.gov/27452608/>

## Chief Executive Officer's Report

### Overview

We have initially focused on the kidney transplantation market, due to the urgent clinical need in this health area. According to the World Health Organisation (WHO), 5-10 million people die annually from kidney disease (compared to 1.8 million who die from the most prominent cancer, lung cancer) and approximately 300,000 people around the world are currently on a waiting list for a kidney transplant, with this number expected to rise due to an increase in kidney disease.

Our kidney transplant assays use advanced next-generation sequencing that we believe can define a personalised risk profile for each patient over the course of their transplant journey and can detect injury in advance of currently available clinical tests, with a view to minimising the risk of transplant rejection.

We believe we have unique kidney transplant diagnostic technology that enables accurate, data-driven support for clinical decisions, such as the most appropriate immunosuppressive therapy for that patient. This has not only near-term scope to reduce the unnecessary and serious consequences from over- or under-dosing for immunosuppression, but also to improve the longevity of transplanted kidneys and, by reducing the risk and rate of transplant failure, much broader potential to deliver huge health economic benefits by improving transplant outcomes.

As we work towards the successful completion of our clinical validation study for Clarava™ and Tuteva™, which we expect to complete by the end of 2021, we have also made considerable progress on other projects, including the CLIA Certification of Registration for our laboratory in Franklin, Tennessee. We also made valuable additions to the Verici Dx team, and expanded our licence agreement with Mount Sinai.

### Pipeline

Our two lead products, Clarava™ and Tuteva™, look to provide insight into how a patient will and is responding to a kidney transplant.

The two products are underpinned by extensive patented and published scientific research from the leading Mount Sinai Medical Center, for which the Company holds an exclusive worldwide licence. Both are currently being evaluated in our collaborative, multi-centre observational clinical validation study, which we are conducting alongside twelve leading US and EU medical centres. The study uses next generation sequencing in the Verici Dx laboratory to create transcriptomic profiles to validate the performance characteristics of the lead Verici Dx RNA signature tests.

We have now completed patient enrolment for the validation study ahead of schedule, and it is our intention that the study for the lead products will be concluded by the end of 2021, in line with expectations set out at IPO. Data is expected to be announced in Q1 2022.

These products are planned to be offered as laboratory developed tests ("LDTs") in the US, due to the lighter regulatory burden of authorisation under the CLIA regime, which is used by CMS (Center for Medicare and Medicaid Services), in partnership with state health departments, rather than seeking clearance from the FDA. In February 2021, we announced the acceleration of our laboratory opening and CLIA approval strategy. This resulted in us achieving CLIA-certification for our newly established laboratory in Tennessee in July, a key step in commercialising our two lead products, subject to a successful conclusion of our validation studies.

### Partnerships and agreements

In January 2021, we expanded the scope of our licence agreement with Mount Sinai to include an additional patent filing related to the analysis of gene expression in a liquid biopsy to predict risk of fibrosis and rejection of the graft. The development of a product that can predict the risk of long-term graft failure, alongside our lead products, would establish an end-to-end solution for clinicians seeking to understand how a patient will and is responding to organ transplant, meeting a critical need for more personalised diagnostic information within transplant care. The product, called Protega™, is currently undergoing patient enrolment for its validation, with enrolment expected to complete by

Q3 2022. The end points of the validation study for this product are expected to be reached up to two years after the completion of enrolment, with data expected shortly thereafter around year-end 2024.

In April 2021, the Company announced that it had entered into an MTA with Mount Sinai and Principal Investigator Dr. Peter Heeger, to allow access to de-identified samples generated from participants from the CTOT-19 study, in an effort to validate the performance and development of commercial tests designed to improve short and long-term graft and patient survival.

The CTOT-19 study, titled: "[\*Effects of Inhibiting at Early Inflammation in Kidney Transplant Patients\*](#)", was initiated in November 2015 with the aim to enrol 300 kidney transplant recipients at 15 transplant centres in the US and Canada, with the study having completed in July 2021.

Access to samples from this important clinical trial, in addition to the Company's clinical validation studies for Clarava™ and Tuteva™, provides Verici Dx with a large and well-characterised sample group. The Company's laboratory will conduct a blinded evaluation of samples in Clarava™ and Tuteva™ and work with investigators, including Dr. Peter Heeger, to characterise results later this year.

### **Management and staff**

Once again, I wish to pay tribute to our colleague and friend, the late Barbara Murphy. She was not only a treasured colleague but a good friend and will be acutely missed by all of us at Verici Dx. She was passionate about the importance of providing innovative solutions to improve patient outcomes and was instrumental in providing the clinical expertise needed to put us firmly on the path towards commercial success. We look forward to honouring her legacy not only from within the Company but also in conjunction with other organisations.

In January 2021, the Company appointed David Schultenover as VP Quality and Regulatory Affairs, to accelerate the CLIA approval process, an essential step to the commercial launch of Clarava™ and Tuteva™. The first step to this was the signing the lease to our new laboratory at the Innovation Park in Franklin, Tennessee in April 2021, which then received CLIA Certification in July. Currently, the Company employs ten full time members of staff.

### **Financials**

Cash balance as at 30 June 2021 was \$14.5m (31 December 2020: \$17.7m), representing a total cash outflow of \$3.4m and a foreign exchange gain of \$0.2m. The most significant expenditure related to the work done to establish our clinical validation study of \$1.0m, excluding related employee cost (period to 31 December 2020: \$0.35m), followed by our total employee cost in the period of \$0.85m, including share-based payment charge of \$0.08m (period to 31 December 2020: \$2.85m including share-based payment charge of \$2.6m). Our spend on laboratory equipment in the period was \$0.5m and \$0.15m was spent on our portfolio of licences and patents.

### **Outlook**

Over the remainder of 2021, we remain focused primarily on the completion of our validation study, for which we recently completed enrolment ahead of schedule. We will now track the participants' progress over the coming months, with completion of the validation study expected at the end of the calendar year. Given our strong cash balance, we will continue to look for any licensing opportunities for complementary technologies that could expand our platform. The Group is also committed to forming new alliances with patient groups and medical associations, to help develop clinical and patient education on the considerable potential benefits of Clarava™ and Tuteva™. Beyond 2021, we look towards the commercial launch of these two lead products, which we expect to execute later in 2022.

**Sara Barrington**  
**Chief Executive Officer**  
13 September 2021

**Consolidated condensed statement of profit or loss and other comprehensive income  
for the six months ended 30 June 2021**

	Note	Six months to 30 June 2021 US\$ Unaudited	Period 22 April to 30 June 2020 US\$ Unaudited	Period 22 April to 31 December 2020 US\$ Audited
Administrative expenses	5	(2,707,703)	(56,500)	(1,595,161)
Exceptional expense – share based payments	5	(128,070)	-	(2,794,625)
Exceptional expense – costs of listing		-	-	(275,508)
<b>Loss from operations</b>		<b>(2,835,773)</b>	(56,500)	(4,665,294)
Finance expense		(3,460)	(27,523)	(69,713)
<b>Loss before tax</b>		<b>(2,839,233)</b>	(84,023)	(4,735,007)
Tax expense		-	-	-
<b>Loss from continuing operations</b>		<b>(2,839,233)</b>	(84,023)	(4,735,007)
<b>Other comprehensive income:</b>				
Exchange gains arising on translation of foreign operations		281,259	-	1,028,907
<b>Loss and total comprehensive income attributable to the owners of the Company</b>		<b>(2,557,974)</b>	(84,023)	(3,706,100)
<b>Earnings per share attributable to the ordinary equity holders of the parent</b>				
<b>Loss per share</b>				
Basic and diluted (US\$ cents)	5	(\$0.02)	(\$84.02)	(\$0.05)

The results reflected above relate to continuing operations

**Consolidated statement of financial position  
as at 30 June 2021**

	Note	30 June 2021 US\$ Unaudited	30 June 2020 US\$ Unaudited	31 December 2020 US\$ Audited
<b>Assets</b>				
<b>Current assets</b>				
Trade and other receivables	9	426,307	-	323,224
Cash and cash equivalents		14,548,980	1	17,751,087
		<u>14,975,287</u>	<u>1</u>	<u>18,074,311</u>
<b>Non-current assets</b>				
Property, plant and equipment	7	911,570	501,957	464,042
Intangible assets	8	1,884,087	1,452,199	1,767,424
		<u>2,795,657</u>	<u>1,954,156</u>	<u>2,231,466</u>
<b>Total assets</b>		<u><b>17,770,944</b></u>	<u><b>1,954,157</b></u>	<u><b>20,305,777</b></u>
<b>Liabilities</b>				
<b>Current liabilities</b>				
Trade and other payables	10	576,961	-	681,890
Loans and borrowings		-	1,873,041	-
<b>NET ASSETS</b>		<u><b>17,193,983</b></u>	<u><b>81,116</b></u>	<u><b>19,623,887</b></u>
<b>Issued capital and reserves attributable to owners of the parent</b>				
Share capital		181,614	1	181,614
Share premium reserve		20,353,748	-	20,353,748
Share-based payments reserve		2,922,695	-	2,794,625
Convertible debt option		-	165,138	-
Foreign exchange reserve		1,310,166	-	1,028,907
Retained earnings		(7,574,240)	(84,023)	(4,735,007)
<b>TOTAL EQUITY</b>		<u><b>17,193,983</b></u>	<u><b>81,116</b></u>	<u><b>19,623,887</b></u>

**Consolidated statement of cash flows  
for the six months ended 30 June 2021**

	Note	Six months to 30 June 2021 US\$ Unaudited	Six months to 30 June 2020 US\$ Unaudited	Period 22 April to 31 December 2020 US\$ Audited
<b>Cash flows from operating activities</b>				
Loss for the period		(2,839,233)	(84,023)	(4,665,294)
<i>Adjustments for:</i>				
Depreciation of property, plant and equipment		121,922	29,527	123,242
Amortisation of intangible fixed assets		60,640	16,317	68,993
Finance expense		3,460	27,523	(69,713)
Share-based payment expense		128,070	-	2,794,625
		(2,525,141)	(10,656)	(1,748,147)
Increase in trade and other receivables		(103,083)	-	(323,224)
(Decrease) / Increase in trade and other payables		(160,083)	-	681,890
Increase in convertible loan		-	10,656	-
Settled by Convertible Loan Note		-	-	535,164
Income taxes paid		-	-	-
<b>Net cash outflow from operating activities</b>		(2,788,307)	-	(854,317)
<b>Cash flows from investing activities</b>				
Purchases of property, plant and equipment	7	(507,783)	-	(25,851)
Purchase of intangibles	8	(154,055)	-	(132,259)
<b>Net cash used in investing activities</b>		(661,838)	-	(158,110)
<b>Cash flows from financing activities</b>				
Issue of ordinary shares		-	1	18,795,500
Expenses of share issue		-	-	(959,993)
Interest paid		(3,460)	-	-
<b>Net cash from financing activities</b>		(3,460)	1	17,835,507
<b>Net increase in cash and cash equivalents</b>		(3,453,605)	1	16,823,080
<b>Cash and cash equivalents at beginning of period</b>		17,751,087	-	-
Exchange gains on cash and cash equivalents		251,498	-	928,007
<b>Cash and cash equivalents at end of year</b>		<b>14,548,980</b>	<b>1</b>	<b>17,751,087</b>



**Consolidated statement of changes in equity  
for the six months ended 30 June 2021**

	Share capital US\$	Share premium US\$	Share-based payment reserve US\$	Convertible debt option US\$	Foreign exchange reserve US\$	Retained earnings US\$	Total attributable to equity holders of parent US\$	Total equity US\$
<b>22 April 2020</b>	<b>1</b>	-	-	-	-	-	<b>1</b>	<b>1</b>
<b>Comprehensive income for the period</b>								
Loss for the period	-	-	-	-	-	(84,023)	(84,023)	(84,023)
<b>Contributions by and distributions to owners</b>								
Issue of convertible note	-	-	-	165,138	-	-	165,138	165,138
<b>At 30 June 2020</b>	<b>1</b>	-	-	<b>165,138</b>	-	<b>(84,023)</b>	<b>81,116</b>	<b>81,116</b>
<b>At 30 June 2020</b>	<b>1</b>	-	-	165,138	-	(84,023)	81,116	81,116
<b>Comprehensive income</b>								
Loss for the period	-	-	-	-	-	(4,650,984)	(4,650,984)	(4,650,984)
Other comprehensive income	-	-	-	-	1,028,907	-	1,028,907	1,028,907
<b>Contributions by and distributions to owners</b>								
Issue of share capital	181,613	20,283,029	-	-	-	-	20,464,642	20,464,642
Conversion of Convertible Loan Note into shares	-	-	-	(94,419)	-	-	(94,419)	(94,419)



**Consolidated statement of changes in equity  
for the six months ended 30 June 2021**

	Share capital US\$	Share premium US\$	Share-based payment reserve US\$	Convertible debt option US\$	Foreign exchange reserve US\$	Retained earnings US\$	Total attributable to equity holders of parent US\$	Total equity US\$
<b>31 December 2020</b>	<b>181,614</b>	<b>20,353,748</b>	<b>2,794,625</b>	-	<b>1,028,907</b>	<b>(4,735,007)</b>	<b>19,623,887</b>	<b>19,623,887</b>
<b>Comprehensive income for the period</b>								
Loss for the period	-	-	-	-	-	(2,839,233)	(2,839,233)	(2,839,233)
Other comprehensive income	-	-	-	-	281,259	-	281,259	281,259
<b>Contributions by and distributions to owners</b>								
Share-based payment	-	-	128,070	-	-	-	128,070	128,070
<b>At 30 June 2021</b>	<b>181,614</b>	<b>20,353,748</b>	<b>2,922,695</b>	-	<b>1,310,166</b>	<b>(7,574,240)</b>	<b>17,193,983</b>	<b>17,193,983</b>

**Notes forming part of the consolidated financial statements  
for the six months ended 30 June 2021**

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**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 historical 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 period ended 31 December 2020. No new IFRS standards, amendments or interpretations became effective in the six months to 30 June 2021.

**Statement of compliance**

This interim consolidated financial information for the six months ended 30 June 2021 has been prepared in accordance with IAS 34, 'Interim financial reporting' and the AIM Rules of UK 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 period ended 31 December 2020, which have been prepared in accordance with International Financial Reporting Standards (IFRS as adopted by the European Union) and have been delivered to the Registrar of Companies. The auditors have reported on those accounts; their report was unqualified, did not include references to any matters to which the auditors drew attention by way of emphasis of matter without qualifying their report 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 2021 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 2020 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.



## 2 Summary of significant accounting policies (*continued*)

### ***Basis of consolidation***

Where the company has control over an investee, it is classified as a subsidiary. The company controls an investee if all three of the following elements are present: power over the investee, exposure to variable returns from the investee, and the ability of the investor to use its power to affect those variable returns. Control is reassessed whenever facts and circumstances indicate that there may be a change in any of these elements of control.

De-facto control exists in situations where the company has the practical ability to direct the relevant activities of the investee without holding the majority of the voting rights. In determining whether de-facto control exists the company considers all relevant facts and circumstances, including:

- The size of the company's voting rights relative to both the size and dispersion of other parties who hold voting rights
- Substantive potential voting rights held by the company and by other parties
- Other contractual arrangements
- Historic patterns in voting attendance.

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.

### **Going concern**

The Group is in the development phase of its business and has not generated any revenues. As at 30 June 2021 the Group had available cash resources of \$14,548,980 following its listing on AIM, a market operated by the London Stock Exchange, on 3 November 2020.

The Board has considered the impact of the ongoing COVID-19 pandemic. There has been minimal impact on the Company to date. Given the impact of COVID-19 in the economy generally, the Board has performed a number of stress tests to assess the ability of the Company to continue as a going concern.

The Directors have prepared cash flow forecasts for the Group for a review period of 12 months from the date of approval of this historical financial information. These forecasts reflect an assessment of current and future market conditions and their impact on the Company's future cash flow performance.

The forecasts have been sensitised for additional costs which may be incurred in the review period. In the sensitised scenario, the forecasts indicate the Company would still have sufficient cash to continue as a going concern.

Having considered the points above, the Directors remain confident in the long-term future prospects for the Group, and their ability to continue as a going concern for the foreseeable future. They therefore adopt the going concern basis in preparing the historical financial information of the Group.

### **Taxation**

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



## **2 Summary of significant accounting policies (continued)**

### ***Current tax***

Current tax payable is based on taxable profit for the year. Taxable profit differs from net profits as reported in the income statement because it excludes items of income or expense that are taxable or deductible in other years and it further excludes items that are never taxable or deductible. The Company's liability for current tax is calculated using tax rates that have been enacted or substantially enacted by the reporting end date.

### ***Deferred tax***

Deferred tax is the tax expected to be payable or recoverable on temporary differences between the carrying amounts of assets and liabilities in the historical financial information and the corresponding tax bases used in the computation of taxable profit, and is accounted for using the balance sheet liability method. Deferred tax liabilities are generally recognised for all taxable temporary differences and deferred tax assets are recognised to the extent that it is probable that taxable profits will be available against which deductible temporary differences can be utilised. Such assets and liabilities are not recognised if the temporary differences arises from goodwill or from the initial recognition of other assets and liabilities in a transaction that affects neither the tax profit nor the accounting profit.

The carrying amount of deferred tax assets is reviewed at each reporting end date and reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered. Deferred tax is calculated at the tax rates that are expected to apply in the period when the liability is settled or the asset is realised. Deferred tax is charged or credited in the income statement, except when it relates to items charged or credited directly to equity, in which case the deferred tax is also dealt with in equity. Deferred tax assets and liabilities are offset when the company has a legally enforceable right to offset current tax assets and liabilities and the deferred tax assets and liabilities relate to taxes levied by the same tax authority.

### ***Share-based payments***

Where equity settled share options are awarded to employees, the fair value of the options at the date of grant is charged to the consolidated statement of comprehensive income over the vesting period. Non-market vesting conditions are taken into account by adjusting the number of equity instruments expected to vest at each reporting date so that, ultimately, the cumulative amount recognised over the vesting period is based on the number of options that eventually vest. Non-vesting conditions and market vesting conditions are factored into the fair value of the options granted. As long as all other vesting conditions are satisfied, a charge is made irrespective of whether the market vesting conditions are satisfied. The cumulative expense is not adjusted for failure to achieve a market vesting condition or where a non-vesting condition is not satisfied.

Where equity instruments are granted to persons other than employees, the consolidated statement of comprehensive income is charged with the fair value of goods and services received.

### ***Foreign currency translation***

#### ***a) Function and presentational currency***

Items included in the financial statements of the Group are measured using USD, the currency of the primary economic environment in which the entity operates ('the functional currency'), which is also the Company's presentation currency.

#### ***b) Transactions and balances***

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such

transactions and from the translation at year-end exchange rates, of monetary assets and liabilities denominated in foreign currencies to USD, are recognised in the income statement.

## **2 Summary of significant accounting policies (continued)**

### **Intangible assets**

Intangible assets are measured at cost less accumulated amortisation and any accumulated impairment losses.

Patents are recognised at fair value at the acquisition date. Patents have a finite useful life and are subsequently carried at cost less accumulated amortisation and impairment losses.

The Company amortises intangible assets with a limited useful life on a straight-line basis. The following rates are applied:

Licence - the shorter of the remaining life of the licence and 15 years

### **Tangible assets**

Tangible fixed assets are stated at cost net of accumulated depreciation and accumulated impairment losses. Costs comprise purchase costs together with any incidental costs of acquisition.

Depreciation is provided to write down the cost less the estimated residual value of all tangible fixed assets by equal instalments over their estimated useful economic lives on a straight-line basis. The following rates are applied:

Plant and machinery - 3 years

The assets' residual values, useful lives and depreciation methods are reviewed, and adjusted prospectively if appropriate, if there is an indication of a significant change since the last reporting date. Low value equipment including computers is expensed as incurred.

### **Impairment of tangible and intangible assets**

At each reporting end date, the Company reviews the carrying amounts of its tangible and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss (if any). Where it is not possible to estimate the recoverable amount of an individual asset, the Company estimates the recoverable amount of the cash-generating unit to which the asset belongs.

The recoverable amount is the higher of fair value less costs to sell and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or cash-generating unit) is reduced to its recoverable amount. An impairment loss is recognised immediately in profit and loss, unless the relevant asset is carried at a revalued amount, in which case the impairment loss is treated as a revaluation decrease.

Where an impairment subsequently reverses, the carrying amount of the asset (or cash-generating unit) is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognised for the asset (or cash-generating unit) in prior years. A reversal of an impairment loss is recognised immediately in profit and loss.

## **2 Summary of significant accounting policies (continued)**

### **Financial instruments**

The Company classifies financial instruments, or their component parts, on initial recognition as a financial asset, a financial liability or an equity instrument in accordance with the substance of the contractual arrangement. Financial assets and financial liabilities are recognised on the statement of financial position when the Company becomes a party to the contractual provisions of the instrument.

#### *a) Financial assets*

Financial assets are classified, at initial recognition, at amortised cost or carrying value. The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Company's business model for managing them.

The classification depends on the purpose for which the financial assets were acquired. Management determines the classification of its financial assets at initial recognition and re-evaluates this classification at every reporting date.

As at the reporting date, the Company did not have any financial assets subsequently measured at fair value.

#### *b) Financial liabilities*

All financial liabilities are initially measured at fair value and, in the case of loans and borrowings, net of directly attributable transaction costs. They are subsequently measured at amortised cost, where applicable, using the effective interest method, with interest expense recognised on an effective yield basis.

#### *c) Cash and cash equivalents*

Cash and cash equivalents comprise cash balances and deposits with a maturity of less than three months at balance sheet date.

### **Provisions**

A provision is recognised in the statement of financial position when the Company has a present legal or constructive obligation as a result of a past event, that can be reliably measured, and it is probably that an outflow of economic benefits will be required to settle the obligation. Provisions are determined by discounting the expected future cash flows at a pre-tax rate that reflects risks specific to the liability.

### **Financing expenses**

Financing expenses comprise interest payable and finance charges on shares classified as liabilities. Foreign exchange gains and losses arising on foreign currency transactions are reported within administrative expenses in the statement of comprehensive income.

Interest payable is recognised in the statement of comprehensive income as it accrues, using the effective interest method.

### **Exceptional items**

Items considered of such significance to enable the reader to better understand the results for the period presented as separately disclosed as exceptional items on the face of the statement of comprehensive income.

## 2 Summary of significant accounting policies (continued)

### Operating segments

The directors are of the opinion that the business of the Group comprises a single activity, that of the development of prognostic and diagnostic tests for kidney transplant patients. Consequently, all activities relate to this segment.

All the non-current assets of the Company are located in, or primarily relate to, the USA

## 3 Judgements and key sources of estimation uncertainty

The preparation of the financial statements requires management to make estimates and judgements that affect the reported amounts of assets, liabilities and costs in the historical financial information. Actual results could differ from these estimates. The judgements, estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant.

Key sources of estimation uncertainty that could cause an adjustment to be required to the carrying amount of assets or liabilities within the next accounting period are:

- Whether impairment is required against the carrying value of tangible and intangible assets
- Amortisation period of license is an estimate based on the expected useful life and is assessed annually for any changes based on current circumstances
- A change in the functional currency from US dollar

## 4 Segment information

The Group has one division being the development of prognostic and diagnostic tests for kidney transplant patients.

## 5 Expenses by nature

	Six months to 30 June 2021 US\$ Unaudited	Period 22 April to 30 June 2020 US\$ Unaudited	Period 22 April to 31 December 2020 US\$ Audited
Employee benefit expenses	848,446	-	2,852,641
Depreciation of property, plant and equipment	121,922	29,527	123,242
Amortisation of intangible assets	60,640	16,317	68,993
Laboratory and development costs	1,043,865	10,656	355,107
Professional costs	455,264	-	553,454
Share-based payment expense for non-employees	43,628	-	200,836
Foreign exchange losses	3,170	-	159,538
Other costs	258,838	-	75,975

## 6 Earnings per share

	Six months to 30 June 2021 US\$ Unaudited	Six months to 30 June 2020 US\$ Unaudited	Period 22 April to 31 December 2020 US\$ Audited
<i>Numerator</i>			
Loss for the period used in basic EPS	(2,839,233)	(84,023)	(4,735,007)
<i>Denominator</i>			
Weighted average number of ordinary shares used in basic EPS	141,747,816	1,000	86,728,156
Resulting loss per share	(US\$0.02)	(US\$84.02)	(US\$0.05)

The Company has one category of dilutive potential ordinary share, being share options (see note 19). The potential shares were not dilutive in the period as the Group made a loss per share in line with IAS 33.

## 7 Tangible assets

Group	Plant & machinery US\$	Total US\$
<i>Cost or valuation</i>		
<b>At 22 April 2020</b>		
Acquired business assets	531,484	531,484
<b>At 30 June 2020</b>		
Additions	25,851	25,851
Foreign exchange movements	36,565	36,565
<b>At 31 December 2020</b>		
Additions	562,938	562,938
Foreign exchange movements	7,907	7,907
<b>At 30 June 2021</b>		
	<b>1,164,745</b>	<b>1,164,745</b>
<i>Accumulated depreciation and impairment</i>		
<b>At 22 April 2020</b>		
Charge for the period	(29,527)	(29,527)
<b>At 30 June 2020</b>		
Charge for the period	(93,715)	(93,715)
Foreign exchange movements	(6,616)	(6,616)
<b>At 31 December 2020</b>		
Charge for the period	(121,922)	(121,922)
Foreign exchange movements	(1,395)	(1,395)
<b>At 30 June 2021</b>		
	<b>(253,175)</b>	<b>(253,175)</b>
<i>Net book value</i>		
<b>At 30 June 2020</b>		
	<b>501,957</b>	<b>501,957</b>
<b>At 31 December 2020</b>		
	<b>464,042</b>	<b>464,042</b>
<b>At 30 June 2021</b>		
	<b>911,570</b>	<b>911,570</b>

## 8 Intangible assets

Group	License US\$	Total US\$
<b>Cost</b>		
<b>At 22 April 2020</b>		
Acquired business assets	1,468,516	1,468,516
	<hr/>	<hr/>
<b>At 30 June 2020</b>		
	<b>1,468,516</b>	<b>1,468,516</b>
Additions	234,095	234,095
Foreign exchange movements	136,584	136,584
	<hr/>	<hr/>
<b>At 31 December 2020</b>		
	<b>1,839,195</b>	<b>1,839,195</b>
Additions	154,055	154,055
Foreign exchange movements	24,032	24,032
	<hr/>	<hr/>
<b>At 30 June 2021</b>		
	<b>2,017,282</b>	<b>2,017,282</b>
	<hr/> <hr/>	<hr/> <hr/>
<b>Accumulated amortisation and impairment</b>		
<b>At 22 April 2020</b>		
Amortisation charge	(16,317)	(16,317)
	<hr/>	<hr/>
<b>At 30 June 2020</b>		
	<b>(16,317)</b>	<b>(16,317)</b>
Amortisation charge	(52,676)	(52,676)
Foreign exchange movements	(2,778)	(2,778)
	<hr/>	<hr/>
<b>At 31 December 2020</b>		
	<b>(71,771)</b>	<b>(71,771)</b>
Amortisation charge	(60,640)	(60,640)
Foreign exchange movements	(784)	(784)
	<hr/>	<hr/>
<b>At 30 June 2021</b>		
	<b>(133,195)</b>	<b>(133,195)</b>
	<hr/> <hr/>	<hr/> <hr/>
<b>Net book value</b>		
<b>At 30 June 2020</b>		
	<b>1,452,199</b>	<b>1,452,199</b>
	<hr/> <hr/>	<hr/> <hr/>
<b>At 31 December 2020</b>		
	<b>1,767,424</b>	<b>1,767,424</b>
	<hr/> <hr/>	<hr/> <hr/>

**At 30 June 2021**

**1,884,087**

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**1,884,087**

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**9 Trade and other receivables**

	<b>30 June 2021 US\$ Unaudited</b>	<b>30 June 2020 US\$ Unaudited</b>	<b>31 December 2020 US\$ Audited</b>
Prepayments	<b>207,476</b>	-	202,546
Other debtors	<b>218,831</b>	-	120,678
	<hr/>	<hr/>	<hr/>
	<b>426,307</b>	-	323,224
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>

**10 Trade and other payables**

	<b>30 June 2021 US\$ Unaudited</b>	<b>30 June 2020 US\$ Unaudited</b>	<b>31 December 2020 US\$ Audited</b>
Trade payables	<b>252,721</b>	-	394,331
Accruals	<b>324,240</b>	-	210,953
Loan	-	-	73,548
	<hr/>	<hr/>	<hr/>
Total financial liabilities classified as financial liabilities measured at amortised cost	<b>576,961</b>	-	678,832
Other payables - tax and social security payments	-	-	3,058
	<hr/>	<hr/>	<hr/>
Total trade and other payables	<b>576,961</b>	-	681,890
	<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.

The loan was interest-bearing at 4% and is repayable by monthly instalment with the last instalment paid in March 2021.

## 11 Share-based payment

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

The SOP 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 and a US sub-plan for the grant of Options to eligible participants in the SOP 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.

	<b>2020</b>	<b>2020</b>
	<b>Weighted average exercise price (p)</b>	<b>Number</b>
Outstanding at 22 April	-	-
Granted during the period	<b>0.32</b>	<b>14,574,782</b>
Exercised during the period	<b>0.20</b>	<b>(10,631,086)</b>
	<hr/>	<hr/>
Outstanding at 31 December 2020 and 30 June 2021	<b>0.32</b>	<b>3,943,696</b>
	<hr/>	<hr/>
Exercisable at 31 December and 30 June 2021	<b>0.32</b>	<b>3,943,696</b>
	<hr/>	<hr/>

The exercise price of options outstanding at 31 December 2020 and 30 June 2021 ranged between 20p and 45.5p and their weighted average contractual life was 2.78 years.

The weighted average fair value of each option granted during the year was 19p.

The fair value of each share option granted has been estimated using a Black-Scholes model and ranges from 10p to 23p. The inputs into the model are a share prices of 20p, 40p and 45.5p, exercise prices of 20p, 40p and 45.5p, expected volatility of 75%, no expected dividend yield, contractual life of between 2.9 and 1.9 years and a risk-free interest rate of 1.1%. As of 31 December 2020, and 30 June 2021, none of the granted stock options have been exercised.

The Group recognised total expenses of \$2,794,625 within administrative expenses relating to equity-settled share-based payment transactions during the period to 31 December 2020 and \$128,070 in the six months to 30 June 2021.

## **12 Related party transactions**

*In the period 22 April to 31 December 2020*

On 4 May 2020, the Company entered into an Asset Purchase Agreement with Renalytix AI Plc (since renamed Renalytix plc) (“Renalytix”). Renalytix is a shareholder in the Company and James McCullough, a Director of the Company, is also a Director and CEO of Renalytix Plc and a shareholder in the Company.

In connection with this transaction the Company also entered into a Convertible Loan Agreement to both fund this transaction and also provide working capital until the admission of the Company’s shares to AIM and the associated fundraising. The total amount advanced under the Convertible Loan Note at the time of its redemption in full into ordinary shares of the Company was \$2,500,000, which converted into 9,831,681 ordinary shares in the Company at redemption on 3 November 2020.

*In the six months to 30 June 2021*

In the period an amount of \$293,119 was paid to Renalytix as full reimbursement for expenses incurred on behalf of the Company.

## **13 Events after the reporting date**

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