

RENALYTIX AI

3 September 2019

Renalytix AI plc
("RenalytixAI", the "Company" or the "Group")

Preliminary results

Renalytix AI plc (AIM: RENX), the AIM listed developer of artificial intelligence-enabled diagnostics for kidney disease, announces its inaugural final results for the period ended June 30, 2019.

Operational highlights

- The U.S. Food and Drug Administration (FDA) granted Breakthrough Device designation in May 2019 for *KidneyIntelX™*, the Company's artificial intelligence clinical *in vitro* diagnostic product for identification of fast progressing kidney disease
- Secured contract agreements, patient blood samples and de-identified electronic health record data for *KidneyIntelX™* expanded clinical validation with University of Pennsylvania, Emory University, and the Icahn School of Medicine at Mount Sinai as participating academic institutions
- Established a Chronic Kidney Disease Advisory Board for *KidneyIntelX™* with clinical experts from Harvard, the Icahn School of Medicine at Mount Sinai, Johns Hopkins, Wake Forest Baptist Health, and Northwestern University
- Established scaled-up production of multiplex plates from *in vitro* diagnostics manufacturer Meso Scale Diagnostics for *KidneyIntelX™*
- Initiated a collaboration with University of Groningen to evaluate *KidneyIntelX™* in 3,500 patients with Type 2 diabetes for early identification and guiding therapeutic treatment for kidney disease
- Executed exclusive license with Mount Sinai for *FractalDx* portfolio of technologies in the field of kidney transplant rejection
- Released positive results for *FractalDx* technology demonstrating ability to predict early rejection in kidney transplant
- Established core investigator groups for *FractalDx* development including leading experts from University of Oxford, Yale University, Emory University, Icahn School of Medicine at Mount Sinai, University of Manitoba, Westmead Hospital Sydney, the Cleveland Clinic and University of Alabama
- Expansion of leadership team with the appointment of Patricia Connolly as vice president of clinical and scientific affairs in February 2019 (now EVP product development), and Thomas McLain as president and chief commercial officer (post period-end)
- Received Clinical Laboratory Improvement Amendments ("CLIA") Certificate Number for Company's New York commercial laboratory from New York State Department of Health, an important initial step in the process towards certifying RenalytixAI to conduct commercial operations for testing patients

Financial highlights

- Completed successful IPO securing net capital financing of approx. \$27m with admission to AIM and trading in the Company's shares starting on 6 November 2018
- In-licensed intellectual property underlying two product technologies, *KidneyIntelX™* and *FractalDx*, for a total of \$11.0m in upfront payments
- c.\$2m capital investment to date in artificial intelligence (AI) technology and clinical assay development
- Net loss of \$6.0m (\$0.16 per ordinary share) for period since inception on 15 March 2018 to 30 June 2019
- Cash used in operations since inception of \$4.4m to 30 June 2019
- Cash on hand of \$9.3m as of 30 June 2019 (prior to 23 July 2019 financing raising net proceeds of \$16.6m)

Post-period end

- The American Medical Association (AMA) granted *KidneyIntelX™* a distinct CPT Code, an important step towards establishing reimbursement from private insurance and Medicare in the U.S.
- Successful interim results reported from multi-center expanded validation study initiated in January 2019 in diabetic chronic kidney disease for *KidneyIntelX™*
- Expanded Chronic Kidney Disease Advisory Board to include leading clinicians from the National Kidney Foundation, the University of Washington and the University of Chicago

- Reported positive results in the Journal of American Society of Nephrology (JASN) for detection of subclinical acute kidney transplant rejection for *FractalDx*
- Completed successful follow-on financing of net \$16.6m on 23 July 2019 through placing of new ordinary shares to a range of new and existing UK and U.S. institutional investors
- Appointed Thomas McLain as president and chief commercial officer
- Continuing to work closely with FDA under Breakthrough Device designation for *KidneyIntelX™* to submit for consideration for regulatory clearance as early as Q4, 2019

Commenting on the outlook for Renalytix, Julian Baines, Non-executive Chairman of Renalytix said:

“We are pleased with the rate of progress made since IPO and are confident that we will continue to deliver key operational milestones in accordance with our plans. Our immediate strategy remains focused on incremental product development, expanding involvement from world leading clinicians, regulatory authority engagement, and building pathways to insurance payer reimbursement in the U.S. Our lead *in vitro* diagnostic programme for detection of fast-progressing kidney disease, *KidneyIntelX™*, is currently under FDA regulatory review and has the potential to address one of the largest unmet medical needs globally, estimated to affect over 850 million people.”

Renalytix AI plc

Julian Baines, Non-executive Chairman

James McCullough, CEO

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Strategic report

To the members of Renalytix AI plc

Review of the business

I am delighted to present the inaugural annual report for Renalytix AI plc, which covers the period from the founding of the Company on 15 March 2018 to 30 June 2019. In order to assist investors with their review of these accounts and as an appropriate basis for future comparison, figures for the 12 months to 30 June 2019 have also been included.

RenalytixAI was created to develop and commercialise artificial intelligence (AI) *in vitro* diagnostics to address one of the largest and costliest disease indications in medicine today. The business was founded in early 2018 on the back of research by leading investigators at the Icahn School of Medicine at Mount Sinai (“Mount Sinai”) and the Joslin Diabetes Center and initially funded by EKF Diagnostics Holdings plc (“EKF”).

On 6 November 2018, the Company achieved a successful initial public offering (IPO), raising net proceeds of approx. \$27m and was admitted to trading on AIM, a market operated by the London Stock Exchange. In May 2019, the U.S. Food and Drug Administration granted *KidneyIntelX™* Breakthrough Device designation. In July 2019, the American Medical Association awarded *KidneyIntelX™* a distinct CPT Code, an important step towards achieving reimbursement from both private insurance payers and Medicare in the United States. Also in July, the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests voted in favour of recommending *KidneyIntelX™* for crosswalk pricing for the 2020 Clinical Laboratory Fee Schedule. While none of these actions guarantee that the Company’s products will achieve regulatory or reimbursement objectives, we continue to believe recent government policy changes and an increasing awareness of the significant public costs associated with chronic kidney disease are favourable for our advanced clinical *in vitro* diagnostic commercialisation and adoption programme in the United States and other countries.

KidneyIntelX™ has demonstrated the ability to significantly improve identification of potentially fast-progressing kidney disease in individuals with Type 2 diabetes and those of African ancestry over methods currently in use. In July 2019, we announced positive interim results from a study conducted with three leading academic medical centres in the United States: the University of Pennsylvania; Emory University; and the Icahn School of Medicine at Mount Sinai. We are working closely with FDA under Breakthrough Device designation to submit final results from this multi-centre study as early as Q4 2019 for regulatory clearance consideration.

After achieving key initial regulatory and reimbursement development milestones and to support a shorter timeline to commercialisation for its lead product *KidneyIntelX™*, the Company raised an additional \$16.6m in net proceeds shortly after the year end, in July 2019. These funds will be used primarily to support the accelerated commercial development and deployment of *KidneyIntelX™*. Additional funds will also be used to support development of the Company's second product portfolio, *FractalDx*, whose first two *in vitro* diagnostics products are being prepared to address key issues in kidney transplant and rejection, and to fund working capital in support of the Company's growth.

We continue to expand discussions with health care providers and insurance payer organisations about *KidneyIntelX™* best deployment practices to improve patient outcomes and reduce cost of care.

We have added to our world-class clinical network to assist with chronic kidney disease and transplant diagnostics product trial design and data evaluation. The network now includes investigators from Harvard, Emory University, Northwestern University, Johns Hopkins, the University of Chicago, the University of Washington, the National Kidney Foundation, Wake Forest Baptist Health, the University of Pennsylvania and Mount Sinai.

We have expanded our leadership team with the appointment of Patricia Connolly as vice president of clinical and scientific affairs in February 2019 (now EVP product development), and Thomas McLain as president and chief commercial officer in July 2019.

Strategy and objectives

In 2018, we secured our cornerstone collaboration with Mount Sinai for product development and intended commercialisation by the Company beginning in the second half of calendar 2019. As part of the collaboration, Mount Sinai became a shareholder in the Company and has subsequently made equity investments both in the IPO and the recent follow-on round.

Separately, in January 2019, the Company executed its option with Mount Sinai for the *FractalDx* license, the Group's second product line, which grants rights to technology and patents relating to a series of potential diagnostics and prognostics in the field of kidney transplant and rejection. We are creating a strategy to develop and, if appropriate, commercialise clinical products incorporating the intellectual property associated with the license. The first two *FractalDx* diagnostic products selected for analytical and clinical validation phase planning beginning this year are a diagnostic for immunosuppressive therapy dosing, and an early kidney transplant rejection diagnostic. As with *KidneyIntelX™*, we have secured a clinical network to advise on trial design and data review, including leading investigators from major transplant centres in the United States, Australia and Canada.

We have advanced our work in machine learning to support *KidneyIntelX™* and our broader technology approach through our partnership with Persistent Systems. Our *in vitro* diagnostics manufacturing partner, Meso Scale Diagnostics, has now delivered the first production lot for measuring the blood-biomarker component of *KidneyIntelX™* to our New York laboratory.

In addition, we have obtained our Clinical Laboratory Improvement Act (CLIA) file number and established a New York laboratory operation (a lease with Johnson & Johnson Innovation, LLC – JLABS). We anticipate applying to New York State for clearance to operate *KidneyIntelX™* as a Laboratory Developed Test for testing on patients within the Mount Sinai system and other New York regional healthcare systems beginning as early as the end of calendar year 2019 and prior to an FDA clearance decision.

Business model

RenalytixAI is working with its partners to develop artificial intelligence-enabled clinical diagnostic solutions for kidney disease. A key element of the development process will be to obtain the required regulatory authorisations. In the first instance we intend to commercialise our products in the USA and have entered discussions with health care providers and insurance payer organisations about best deployment practices to improve patient outcomes and reduce cost of care, whilst at the same time solidifying the most optimal routes to market. Following success in the USA we will consider commercialisation in other territories.

Key performance indicators

The Group focuses on assay development and operating/administrative costs relative to plan as key performance indicators, as well as cash position. Once test sales commence, revenue, gross margin and adjusted EBITDA will be added as performance indicators, as well as certain relevant non-financial measures.

Financial review

Income statement

The Group is currently in its initial development phase and therefore has not yet commenced revenue generation. The Group's presentational currency is the United States Dollar.

Administrative costs

The largest elements of administrative costs are employee related expenses (\$1.48m), research and development costs (\$1.93m), and depreciation and amortization costs (\$1.13m). In addition to the charge to income, development costs including trade secrets of \$8.38m have been capitalized, mainly resulting from the acquisition of the biomarker business from EKF, as well as the development work relating to the AI software.

Finance income

The Group has finance income as the Group has largely been funded by equity, and interest earned on cash deposits has outweighed the interest costs on the start-up loans from EKF.

Balance sheet

Fixed assets

Property, plant and equipment consists of laboratory equipment being used to support the product development activities.

Intangible assets

Includes payments made primarily to Mount Sinai for license and patent costs for the intellectual property underlying KidneyIntelX™ and FractalDx, as well as amounts capitalized as development costs. Intangible assets also include the value of the biomarker business purchased (in exchange for Ordinary shares in the Company) from EKF.

Deferred tax

A deferred tax asset has been calculated based on the accumulated tax losses in the USA.

Borrowings

The Group has no long-term debt outstanding as of 30 June 2019. Prior to the admission of the Company's shares to trading on AIM and the associated equity financing, EKF loaned the Company \$0.44m to fund operations, which was repaid (including nearly \$20,000 in interest) in November 2018.

Capitalization

The Company completed a public listing on the AIM market on 6 November, 2018 and associated equity financing of \$26.8m net of fees and related charges.

Post balance sheet event

On 23 July 2019 the Company successfully completed a secondary public offering, raising \$16.6m net of expenses.

Future developments and outlook

We are pleased with the rate of progress made since IPO and are confident that we will continue to deliver key operational milestones in accordance with our plans. Our immediate strategy remains focused on incremental product development, expanding involvement from world leading clinicians, regulatory authority engagement, and building pathways to insurance payer reimbursement in the U.S. Our lead *in vitro* diagnostic programme for detection of fast-progressing kidney disease, *KidneyIntelX™*, is currently under FDA regulatory review and has the potential to address one of the largest unmet medical needs globally, estimated to affect over 850 million people.

In April 2019, we published a manuscript which outlines positive results from a study in approximately 870 patients that demonstrated the performance characteristics of our machine learning algorithm combining blood biomarkers and de-identified electronic health record data to predict fast progressing kidney disease. In July 2019, we announced positive interim results from a multi-centre clinical study with *KidneyIntelX™* that confirmed results we had demonstrated in the April 2019 single-centre study. We believe study data on the algorithm at the core of *KidneyIntelX™* could lead to a significant improvement in identification of patients likely experiencing a rapid kidney function decline versus what is currently achievable with standard clinical models. We believe that the published data from this study, with expanded clinical validation, could help clinicians identify the patients who would benefit most from early and more aggressive treatment to mitigate kidney disease progression, which could result in substantial cost savings for health care systems world-wide.

The Company is evaluating its plans for *FractalDx* and intends to begin the commercial development process on two diagnostic products addressing key unmet needs in kidney transplant this year.

We remain confident in the prospects for the business and look forward to providing further updates on our progress.

Julian Baines

Non-executive Chairman

3 September 2019

**CONSOLIDATED INCOME STATEMENT
FOR THE PERIOD ENDED 30 JUNE 2019**

	Note	Period from inception to 30 June 2018 \$'000	Year to 30 June 2019 \$'000	Period from inception to 30 June 2019 \$'000
Continuing operations				
Administrative expenses		(418)	(6,537)	(6,955)
Operating loss		(418)	(6,537)	(6,955)
Finance income - net	3	-	19	19
Loss before tax		(418)	(6,518)	(6,936)
Taxation	4	-	959	959
Loss for the period		(418)	(5,559)	(5,977)
Earnings per Ordinary share from continuing operations				
Basic and diluted	5	\$ (0.01)	\$ (0.15)	\$ (0.16)

**CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME
FOR THE PERIOD ENDED 30 JUNE 2019**

	Period from inception to 30 June 2018 \$'000	Year to 30 June 2019 \$'000	Period from inception to 30 June 2019 \$'000
Loss for the period – continuing operations	(418)	(5,559)	(5,977)
Other comprehensive income:			
Items that may be subsequently reclassified to profit or loss			
Currency translation differences	3	(598)	(595)
Other comprehensive loss for the period	3	(598)	(595)
Total comprehensive loss for the period	(415)	(6,157)	(6,572)

**CONSOLIDATED AND COMPANY'S STATEMENT OF FINANCIAL POSITION
AS AT 30 JUNE 2019**

		Group As at 30 June 2018 \$'000	Group As at 30 June 2019 \$'000
Assets			
Non-current assets			
Property, plant and equipment	7	-	278
Intangible assets	8	-	18,287
Deferred tax assets	4	-	959
Total non-current assets		<u>-</u>	<u>19,524</u>
Current Assets			
Security deposits		-	49
Prepaid and other current assets		7	61
Cash and cash equivalents		82	9,288
Total current assets		<u>89</u>	<u>9,398</u>
Total assets		<u>89</u>	<u>28,922</u>
Equity attributable to owners of the parent			
Share capital		66	175
Share premium		-	34,032
Share-based payment reserve		-	532
Foreign currency reserves		3	(595)
Retained earnings		(418)	(5,977)
Total equity		<u>(349)</u>	<u>28,167</u>
Liabilities			
Current liabilities			
Trade and other payables		-	755
Borrowings		438	-
Total liabilities		<u>438</u>	<u>755</u>
Total equity and liabilities		<u>89</u>	<u>28,922</u>

**CONSOLIDATED STATEMENT OF CASH FLOWS
FOR THE PERIOD ENDED 30 JUNE 2019**

	Group Period from inception to 30 June 2018 \$'000	Group Year to 30 June 2019 \$'000	Group Period from inception to 30 June 2019 \$'000
Cash flow from operating activities			
Loss before income tax	(418)	(6,518)	(6,936)
<i>Adjustments for</i>			
- Depreciation	-	31	31
- Amortisation and impairment charges	-	1,094	1,094
- Share-based payments	-	532	532
<i>Changes in working capital</i>			
- Trade and other receivables	-	218	218
- Prepaid assets and other current assets	(4)	(57)	(61)
- Security Deposits	-	(49)	(49)
- Trade and other payables	-	755	755
Cash used in operations	<u>(422)</u>	<u>(3,994)</u>	<u>(4,416)</u>
Interest paid	-	-	-
Net cash used in operating activities	<u>(422)</u>	<u>(3,994)</u>	<u>(4,416)</u>
Cash flow from investing activities			
Purchase of property, plant and equipment (PPE)	-	(308)	(308)
Purchase of intangibles	-	(12,741)	(12,741)
Net cash used in investing activities	<u>-</u>	<u>(13,049)</u>	<u>(13,049)</u>
Cash flow from financing activities			
Issue of shares (net of issue costs)	66	26,687	26,753
Proceeds from loans	438	-	438
Repayment of loans	-	(438)	(438)
Net cash generated from financing activities	<u>504</u>	<u>26,249</u>	<u>26,753</u>
Net increase in cash and cash equivalents	<u>82</u>	<u>9,206</u>	<u>9,288</u>
Cash and cash equivalents at beginning of period	-	82	-
Cash and cash equivalents at end of period	<u>82</u>	<u>9,288</u>	<u>9,288</u>

**CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
FOR THE PERIOD ENDED 30 JUNE 2019**

	Share Capital	Share Premium	Share- based payment reserve	Foreign Currency Reserve	Retained earnings	Total equity
	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
At 15 March 2018						
Comprehensive income	-	-	-	-	-	-
Loss for the period	-	-	-	-	(5,977)	(5,977)
Other comprehensive income						
Currency translation differences	-	-	-	(595)	-	(595)
Total comprehensive income	-	-	-	(595)	(5,977)	(6,572)
Transactions with owners						
Issue of shares	175	35,522	-	-	-	35,697
Less issue costs	-	(1,490)	-	-	-	(1,490)
Share-based payments	-	-	532	-	-	532
Total transactions with owners of the parent, recognized directly in equity	175	34,032	532	-	-	34,739
At 30 June 2019	175	34,032	532	(595)	(5,977)	28,167

NOTES TO THE FINANCIAL STATEMENTS

1. General information and basis of presentation

Renalytix AI Plc is a company incorporated in the United Kingdom. The Company is a public limited company, which is listed on the AIM market of the London Stock Exchange. The address of the registered office is Avon House, 19 Stanwell Road, Penarth, Cardiff CF64 2EZ. The Company was incorporated on 15 March 2018 and its registered number is 11257655.

The principal activity of the Company and its subsidiary (together “the Group”) is as a developer of artificial intelligence-enabled diagnostics for kidney disease.

The financial statements are presented in United States Dollars (USD) because that is the currency of the primary economic environment in which the Group operates.

The audited preliminary announcement been prepared in accordance with International Financial Reporting Standards as adopted by the European Union (IFRSs), IFRS IC interpretations and the Companies Act 2006 applicable to companies reporting under IFRS. This preliminary announcement was approved by the Board of Directors on 3 September 2019. The preliminary announcement does not constitute statutory financial statements within the meaning of section 434 of the Companies Act 2006. No earlier statutory accounts have been prepared or delivered.

Certain statements in this announcement constitute forward-looking statements. Any statement in this announcement that is not a statement of historical fact including, without limitation, those regarding the Company’s future expectations, operations, financial performance, financial condition and business is a forward-looking statement. Such forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially. These risks and uncertainties include, amongst other factors, changing economic, financial, business or other market conditions. These and other factors could adversely affect the outcome and financial effects of the plans and events described in this announcement and the Company undertakes no obligation to update its view of such risks and uncertainties or to update the forward-looking statements contained herein. Nothing in this announcement should be construed as a profit forecast.

While the financial information included in this preliminary announcement has been prepared in accordance with the recognition and measurement criteria of International Financial Reporting Standards (IFRSs), this announcement does not itself contain sufficient information to comply with IFRSs. The Company will publish its full financial statements for the period ended 30 June 2019 by 7 September 2019, which will be available on the Company's website at www.renalytixai.com and at the Company's registered office at Avon House, 19 Stanwell Road, Penarth, Cardiff CF64 2EZ. The Annual General Meeting will be held on Monday 30 September 2019.

2. Segmental reporting

The Group operates as a single segment.

As the Group is at the early stages of its development, there are no revenues.

3. Significant accounting policies

The principal accounting policies applied in the preparation of these financial statements are set out below.

Going concern

The Group and Company meet their day-to-day working capital requirements through the use of cash reserves.

The Directors have considered the applicability of the going concern basis in the preparation of these financial statements. This included the review of internal budgets and financial results which show, taking into account reasonably probable changes in financial performance, that the Group and Company should be able to operate within the level of its current funding arrangements.

The Directors believe that the Group and the Company have adequate resources to continue in operation for the foreseeable future. For this reason they have adopted the going concern basis in the preparation of the interim financial statements.

Basis of consolidation

The consolidated financial statements incorporate the financial statements of the Company and its subsidiary undertaking. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. The existence and effect of potential voting rights that are currently exercisable or convertible are considered when assessing whether the Group controls another entity.

Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are de-consolidated from the date that control ceases.

The Group uses the acquisition method of accounting to account for business combinations. The consideration transferred for the acquisition of a subsidiary is the fair values of the assets transferred, the liabilities incurred and the equity interests issued by the Group. The consideration transferred includes the fair value of any asset or liability resulting from a contingent consideration agreement. Acquisition related costs are expensed as incurred. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date.

On 23 October 2018, as part of a pre-admission re-organisation, the Company acquired the entire share capital of Renalytix AI, Inc., then a subsidiary of EKF. Given common ownership of the Company and the subsidiary from incorporation up to the date of legal ownership, the transaction has been treated as a group reorganisation with no fair value adjustments to assets or liabilities. The subsidiary has been consolidated within the results of the Group from the date of incorporation.

Inter-Company transactions, balances and unrealised gains on transactions between Group companies are eliminated. Unrealised losses are also eliminated. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

Foreign currency translation

(a) Functional and presentational currency

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in United States Dollars, which is the Group's presentational currency. The functional currency of the parent Company is GB Pounds.

(b) Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions where items are re-measured. 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 are recognised in the income statement within 'administrative expenses'.

(c) Group companies

The results and financial position of all the Group entities that have a functional currency different from the presentational currency are translated into the presentational currency as follows:

- assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet;
- income and expenses for each income statement are translated at average exchange rates; and
- all resulting exchange differences are recognised in other comprehensive income.

On consolidation, exchange differences arising from the translation of the net investment in foreign operations are taken to other comprehensive income. When a foreign operation is partially disposed of or sold, exchange differences that were recorded in equity are recognised in the income statement as part of the gain or loss on sale.

Segmental reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Executive Directors who make strategic decisions. At present the Directors consider the business to operate in a single segment.

Property, plant and equipment

Property, plant and equipment are stated at historical cost less accumulated depreciation and any provision for impairment. Historical cost includes expenditure that is directly attributable to the acquisition of the asset and bringing the asset to its working condition for its intended use.

Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only where it is probable that future economic benefits associated with the asset will flow to the Group and the cost of the asset can be measured reliably. The carrying amount of the replaced part is derecognised. All other repairs and maintenance are charged to the income statement during the financial period in which they are incurred.

Depreciation on assets is calculated using the straight-line method to allocate their cost to their residual values over their estimated useful lives, as follows:

Fixtures and fittings 20%

The assets' residual values and useful economic lives are reviewed regularly, and adjusted if appropriate, at the end of each reporting period.

An asset's carrying value is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on the disposal of assets are determined by comparing the proceeds with the carrying amount and are recognised in administration expenses in the income statement.

Intangible assets

(a) Trademarks, trade names and licences

Separately acquired trademarks and licences are shown at historical cost. Trademarks and licences acquired in a business combination are recognised at fair value at the acquisition date. Trademarks and licences have a finite useful life and are carried at cost less accumulated amortisation. Amortisation is calculated using the straight-line method to allocate the cost of trademarks and licences over the contractual licence period of 10-15 years and is charged to administrative expenses in the income statement.

(b) Development costs and trade secrets

Development costs have a finite useful life and are carried at cost less accumulated amortisation.

Expenditure incurred on the development of new or substantially improved products or processes is capitalised, provided that the related project satisfies the criteria for capitalisation, including the project's technical feasibility and likely commercial benefit. All other research and development costs are expensed to profit or loss as incurred.

Development costs are amortised over the estimated useful life of the products with which they are associated. Amortisation commences when a new product is in commercial production. The amortisation is charged to administrative expenses in the income statement. The estimated remaining useful lives of development costs are reviewed at least on an annual basis.

The carrying value of capitalised development costs is reviewed for potential impairment at least annually and if a product becomes unviable and an impairment is identified the deferred development costs are immediately charged to the income statement. Amortisation has not yet commenced.

Trade secrets, including technical know-how, operating procedures, methods and processes, are recognised at fair value at the acquisition date. Trade secrets have a finite useful life and are carried at cost less accumulated amortisation. Amortisation has not yet commenced.

Impairment of non-financial assets

Assets that have an indefinite life or where amortisation has not yet commenced are tested annually for impairment. Assets that are subject to amortisation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the carrying amount exceeds its recoverable amount.

The recoverable amount is the higher of an asset's 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.

For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows. Impairment losses recognised for cash-generating units, to which goodwill has been allocated, are credited initially to the carrying amount of goodwill. Any remaining impairment loss is charged pro rata to the other assets in the cash-generating unit.

Where an impairment loss subsequently reverses, the carrying amount of the asset (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 (cash-generating unit) in the prior period. A reversal of an impairment loss is recognised in the income statement immediately. If goodwill is impaired however, no reversal of the impairment is recognised in the financial statements.

Financial assets

Classification

The Company classifies its financial assets in the following categories: loans and receivables at amortised cost and financial assets at fair value through profit or loss. The classification depends on the purpose for which the financial assets were acquired and management determines the classification of its financial assets at initial recognition.

(a) Loans and receivables

Financial assets are classified as at amortised cost only if both of the following criteria are met: the asset is held within a business model whose objective is to collect contractual cash flows, and the contractual terms give rise to cash flows that are solely payments of principal and interest. Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted on an active market. They are included in current assets, except for maturities greater than 12 months after the balance sheet date. These are classified as non-current assets. The Company's loans and receivables comprise 'trade and other receivables' and cash and cash equivalents in the balance sheet.

(b) Financial assets at fair value through profit or loss

The Group classifies the following financial assets at fair value through profit or loss (FVPL):

- debt investments that do not qualify for measurement at either amortised cost or fair value through Other Comprehensive Income;
- equity investments that are held for trading, and
- equity investments for which the entity has not elected to recognise fair value gains and losses through Other Comprehensive Income.

(c) Financial assets at fair value through other comprehensive income

Financial assets at fair value through other comprehensive income comprise equity securities that are not held for trading and which the Group has irrevocably elected at initial recognition to recognise in this category. The Group considers this category to be more relevant for assets of this type.

Cash and cash equivalents

Cash and short-term deposits in the balance sheet comprise cash at bank and in hand and short-term deposits with an original maturity of three months or less.

For the purposes of the cash flow statements, cash and cash equivalents consist of cash and short-term deposits as defined above.

Share capital and premium

Ordinary Shares are classified as equity. Proceeds in excess of the nominal value of shares issued are allocated to the share premium account and are also classified as equity. Incremental costs directly attributable to the issue of new Ordinary Shares or options are deducted from the share premium account.

Other reserves - equity

The share-based payment reserve is used to recognise the fair value of equity settled share-based payment transactions.

Foreign currency reserve is used to record the exchange differences on translation of entities in the Group which have a functional currency different to the presentation currency.

Retained earnings includes all current and prior period results as disclosed in the income statement.

Trade and other payables

Trade payables are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Accounts payable are classified as current liabilities if payment is due within one year or less (or in the normal operating cycle of the business if longer). If not, they are presented as non-current liabilities. Trade payables are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method.

Current and deferred income tax

Income tax comprises current and deferred tax. Tax is recognised in the income statement, except to the extent that it relates to items recognised in other comprehensive income where the associated tax is also recognised in other comprehensive income.

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the balance sheet date in the countries where the Company and its subsidiary operate and generate taxable income. Management evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation and establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Deferred tax is recognised, using the liability method, on all temporary differences at the balance sheet date between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes. Deferred tax liabilities are recognised in respect of all temporary differences except where the deferred tax liability arises from the initial recognition of goodwill in business combinations.

Deferred tax assets are recognised for all deductible temporary differences, carry-forward of unused tax assets and tax losses, to the extent that they are regarded as recoverable. They are regarded as recoverable where, on the basis of available evidence, there will be sufficient taxable profits against which the future reversal of the underlying temporary differences can be deducted.

The carrying value of the amount of deferred tax assets is reviewed at each balance sheet date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all, or part, of the tax asset to be utilised.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the year when the asset is realised or the liability is settled, based on the tax rates (and tax laws) that have been substantively enacted at the balance sheet date.

Deferred income tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and when the deferred income tax assets and liabilities relate to income taxes levied by the same taxation authority on either the taxable entity or different taxable entities where there is an intention to settle the balances on a net basis.

Employee benefits

(a) Pension obligations

The Group makes contributions to defined contribution pension plans. A defined contribution plan is a pension plan under which the Group pays fixed contributions into a separate entity with the pension cost charged to the income statement as incurred. The Group has no further obligations once the contributions have been paid.

(b) Share-based compensation

The Group operates an equity-settled, share-based compensation plan, under which the Group receives services from employees and others as consideration for equity instruments of the Group. Equity-settled share-based payments are measured at fair value at the date of grant and are expensed over the vesting period based on the number of instruments that are expected to vest. For plans where vesting conditions are based on share price targets, the fair value at the date of grant reflects these conditions. Where applicable the Group recognises the impact of revisions to original estimates in the income statement, with a corresponding adjustment to equity for equity-settled schemes. Fair values are measured using appropriate valuation models, taking into account the terms and conditions of the awards.

When the share-based payment awards are exercised, the Company issues new shares. The proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium.

National insurance on share options

To the extent that the share price at the balance sheet date is greater than the exercise price on options granted to UK citizens under unapproved share-based payment compensation schemes, provision for any National Insurance Contributions has been based on the prevailing rate of National Insurance. The provision is accrued over the performance period attaching to the award.

Interest income

Interest income is accrued on a time basis, by reference to the principal outstanding and at the effective interest rate applicable, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to that asset's net carrying amount.

Exceptional items

These are items of an unusual or non-recurring nature incurred by the Group and include transactional costs and one-off items relating to business combinations, such as acquisition expenses.

4. Finance income and costs

	Period ended 30 June 2019
	\$'000
Finance costs:	
Interest expense	20
Finance income:	
Interest income	(34)
Other income	(5)
Net finance income	(19)

5. Income tax

	Period ended 30 June 2019
Group	\$'000
Deferred tax	959
Total deferred	959
Income tax credit	959

The Finance Act 2015 which was substantively enacted in 2015 included legislation to reduce the main rate of UK corporation tax to 19% from 1 April 2017 and the Finance Act 2016 which was substantively enacted in 2016 included legislation to reduce the main rate of UK corporation tax to 17% from 1 April 2020.

The tax on the Group's loss before tax differs from the theoretical amount that would arise using the standard tax rate applicable to the losses of the consolidated entities as follows:

	Period ended 30 June 2019 \$'000
Loss before tax	6,936
Tax calculated at the UK standard rate of tax of 19%	1,318
Tax effects of:	
Expenses not deductible for tax purposes	(102)
Losses on which no deferred tax asset is recognised	(257)
Tax credit	<u>959</u>

There are no tax effects on the items in the statement of other comprehensive income.

Deferred tax assets are recognized based on subsidiary net losses based on the US corporate tax rate of 21%. Net losses can be carried forward indefinitely to offset future taxable profits. No deferred asset is calculated on losses in the UK totalling \$1,654,000 where the probability of future utilisation is considered too remote.

6. Earnings per share

Basic earnings per share is calculated by dividing the loss attributable to equity holders of the parent by the weighted average number of ordinary shares in issue during the period.

	Period ended 30 June 2019 \$'000
Loss attributable to owners of the parent	(5,977)
Weighted average number of ordinary shares in issue	<u>37,332,983</u>
Basic and diluted loss per share	<u>\$ (0.16)</u>

The Company was incorporated on 15 March 2018 with 50,000 ordinary shares of £1.00 each, and as a result of subdivisions (100:1 on 4 May 2018 and then 4:1 on 24 October 2018), the resulting founding shares became 20,000,000 at £0.0025 each.

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.

7. Dividends

No dividends to shareholders of the holding company were provided or paid during the period to 30 June 2019. The Board's policy is to enhance shareholder value mainly through the growth of the Group, which is currently in the early stages of its development. The Board will however consider the payment of dividends if and when appropriate.

8. Property, plant, and equipment

Group	Fixtures and fittings \$'000
Cost	
At beginning of period	-
Additions	309
Exchange differences	
At 30 June 2019	309
Depreciation	
At beginning of period	-
Charge for the period	31
Exchange differences	
At 30 June 2019	31
Net book value	
At 30 June 2019	278

The depreciation charge of \$31,482 has been charged to administration expenses.

9. Intangible fixed assets

Group	Trademarks trade names & licences \$'000	Trade secrets \$'000	Development costs \$'000	Total \$'000
Cost				
At beginning of period	-	-	-	-
Additions	10,997	6,644	1,740	19,382
Foreign translation	5	(3)	-	2
At 30 June 2019	11,002	6,641	1,740	19,383
Amortisation				
At beginning of period	-	-	-	-
Charge for the period	1,095	-	-	1,095
Foreign translation	1	-	-	1
At 30 June 2019	1,096	-	-	1,096
Net book value				
At 30 June 2019	9,906	6,641	1,740	18,287

10. Subsequent events

On 23 July 2019, the Company raised additional funds of \$16.6m after expenses through the issue of 5,600,000 new ordinary shares at a price of £2.50 (\$3.11) per share to a range of new and existing UK and US institutional investors.