3 March 2020

This announcement contains inside information

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

Half-year Report

Renalytix AI plc (LSE: RENX), the AIM-traded developer of clinical grade artificial intelligence *in vitro* diagnostics for kidney disease, announces its unaudited interim results for the six months ended 31 December 2019, a period of considerable progress in advancing the processes of regulatory and reimbursement approval and preparing for commercialisation.

Operational highlights

- CPT reimbursement code 0105U for *KidneyIntelX*™ became effective across the US on 1 October 2019
- Medicare national pricing for *KidneyIntelX*™ set at $950 per reportable test result
- First positive coverage insurance payor determination
- Medicare coverage determination process initiated with results expected H1 calendar 2021
- Regulatory review processes for *KidneyIntelX*™ continue on track
- Completed 3,500-patient diabetic kidney disease study evaluating the effectiveness of *KidneyIntelX*™
- Key leadership appointments including Dr. Chirag Parikh (Non-Executive Director) and Thomas McLain (President & Chief Commercial Officer)
- Additional key operating hires to support commercial operations
- Expansion of intellectual property portfolio
- Advancing commercial discussions with additional insurance payors and healthcare providers
- US Presidential Executive Order, *Advancing American Kidney Health*, prioritizes the need for transformation in the prevention and treatment of kidney disease

Financial highlights

- Placing of new ordinary shares raising gross proceeds of £14.0m ($17.4m) at price per share of 250p ($3.11), a 106% premium to the IPO price per share of 121p ($1.51)
- Cash and equivalents on hand as at 31 December 2019: $20.8m (31 December 2018: $13.1m; 30 June 2019: $9.3m)
- $1.9m invested in assay development, laboratory equipment and clinical validation during the period ($3.5m invested since inception)
- Net loss after tax for the period of $3.8m, in line with expectations and reflecting continuing investment in key development, regulatory and commercialisation activities (H1 FY 2019: $2.5m)

Post-period end developments

- CLIA Certificate of Registration received to initiate commercial testing for newly established commercial laboratory in Utah
- Mount Sinai electronic medical record (EMR) system integration initiated for *KidneyIntelX*™
- Possible spin-out and admission to AIM of *FractalDx* under consideration

Commenting on the outlook for RenalytixAI, Julian Baines, Non-executive Chairman of Renalytix said:
"Our Company continues to execute on key milestones that we believe will provide a strong foundation for market adoption of KidneyIntelX™ and sustainable growth. The environment and timing for the anticipated national roll-out in 2020 is supportive, as combating kidney disease in large patient populations has become a top priority for governments, private payors and healthcare providers alike. Live operations with our launch partner, Mount Sinai Health System, are on schedule for the second quarter of this calendar year and, if successful, will help validate our business-to-business partnership model for deployment at other major health care providers."

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The person responsible for this announcement is James McCullough, CEO of RenalytixAI.

About Kidney Disease

Kidney disease is now recognised as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control and Prevention (CDC) estimates that 15% of US adults, or 37 million people, currently have chronic kidney disease (CKD). Further, the CDC reports that 9 out of 10 adults with CKD do not know they have it and 1 out of 2 people with very low kidney function who are not on dialysis do not know they have CKD*. Kidney disease is referred to as a "silent killer" because it often has no symptoms and can go undetected until a very advanced stage. Each year kidney disease kills more people than breast and prostate cancer. Every day, 13 patients in the United States die while waiting for a kidney transplant.

* https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html

About RenalytixAI

RenalytixAI is a developer of clinical grade, artificial intelligence-enabled *in vitro* diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. The Company's products are being designed to make significant improvements in kidney disease diagnosis, transplant management, clinical care, and patient stratification for drug clinical trials. For more information, visit renalytixai.com

CHAIRMAN'S BUSINESS REVIEW

I am delighted to present the interim report for the six months ended 31 December 2019 for Renalytix AI plc.

About RenalytixAI

RenalytixAI was created to develop clinical grade artificial intelligence *in vitro* diagnostic solutions to address kidney disease, one of the most common and costly chronic medical conditions globally. The company was founded in early 2018 on the back of research by leading nephrologists at the Icahn School of Medicine at Mount Sinai ("Mount Sinai") and initially funded by EKF Diagnostics Holdings plc ("EKF"). The Company was admitted to AIM, a market of the London Stock Exchange, on 6 November 2018, and is focused on product development and commercialisation preparations for its two key products in the area of kidney disease:

***KidneyIntelX*™**

The Company's lead product, *KidneyIntelX*™, is a clinical grade, artificial intelligence *in vitro* diagnostic ("AI-IVD") solution. We believe *KidneyIntelX*™ is one, if not the first, example of an artificial intelligence clinical solution with a defined price and reimbursement code, capable of being paid for by US health insurance system coverage. Further, we believe *KidneyIntelX*™ will represent one, if not the first, regulated AI-IVD products for use with patients if approved for commercial use by regulators this year.

KidneyIntelX™ is designed to provide early identification of Rapid Kidney Function Decline ("RKFD") and kidney failure in chronic kidney disease ("CKD") patients with Type 2 diabetes and patients of African ancestry. *KidneyIntelX*™ uses a machine-learning algorithm that combines different sources of predictive data including blood-based biomarkers and features from a patient's electronic health record to generate a predictive risk score. To date we have exceeded our own expectations in terms of the time taken to reach key commercial milestones including product performance validation, advancement of state and federal regulatory process, national Medicare pricing, and private insurance payor reimbursement process in the United States.

We believe this positive performance is bolstered in part because of our potentially first-in-class AI-IVD product position, a significant shift in government policy capped by the US Presidential Executive Order on *Advancing American Kidney Health* in July 2019, and the rising strategic priority of private payors and healthcare providers to effectively treat kidney disease. The Board is pleased with the broad-based support that *KidneyIntelX*™ is attracting from leading clinicians and believes that population-based adoption has strong potential to support a key policy initiative to reduce the number of Americans developing end-stage renal disease ("ESRD") by 25% by 2030. Our multi-centre validation study data supports *KidneyIntelX*™ as a compelling solution to drive earlier intervention in kidney disease, before a patient reaches ESRD.

FractalDx

The Company's *FractalDx* technology portfolio of diagnostic and prognostic products is based on extensive scientific research findings published in leading clinical journals, in-licensed from Mount Sinai in late 2018. The *FractalDx* technology is based principally on sequencing biomarkers from a patient's blood using widely available instrument platforms. The Company is actively developing two products from the portfolio: a prognostic test performed prior to transplant to predict which transplant recipients are most at risk of acute rejection and a diagnostic test for evidence of rejection of the transplanted kidney in advance of any clinical symptoms. Both tests will be instrumental in guiding patient care including immunosuppression therapy dosing to mitigate the toxic side effects and damage to the transplanted kidney due to excessive dosing.

Operational progress

In the six months ended 31 December 2019, the Company made considerable progress in advancing *KidneyIntelX*™ through the regulatory and reimbursement approval processes, and in its preparations for potentially national scale commercial operations.

Reimbursement

A distinct Common Procedural Terminology ("CPT") reimbursement code 0105U became effective on 1 October 2019 and can be used to report the use of *KidneyIntelX*™ testing services to private and public payors throughout

the United States for reimbursement. This was followed by the release of the Final 2020 Clinical Laboratory Fee Schedule ("CLFS") by the Centers for Medicare and Medicaid Services ("CMS") which set a national price for *KidneyIntelX*™at $950 per reportable test result. This price became effective on 1 January 2020 and will remain in effect for a three-year term until December 2022, after which Medicare pricing will be reset to the prevailing average private market insurance reimbursement price established.

We expect the inclusion of *KidneyIntelX*™on CMS's CLFS to help accelerate RenalytixAI's contracting efforts with private insurance payors, as several large insurance plans in the United States use Medicare's CLFS to determine test pricing. Based on this development, RenalytixAI plans to expand the market focus for *KidneyIntelX*™ to a US nationwide programme, with a significant expansion in covered lives expected to take place beginning in calendar year 2020 and extending through 2021.

We were also pleased to announce the first positive private insurance payor coverage determination for *KidneyIntelX*™. In October 2019, Capital District Physicians' Health Plan, Inc. ("CDPHP"), a physician-led health insurance payor, adopted coverage determination policies that will provide *KidneyIntelX*™ for qualified CDPHP members who have Type 2 diabetes and CKD, or diabetic kidney disease ("DKD"). In the United States, approximately 12 million people currently have DKD. Our goal is to work with additional insurance payors and healthcare providers to expand coverage determinations for *KidneyIntelX*™. In addition, the submission process to attain Medicare coverage determination for *KidneyIntelX*™ at $950 per reportable test result on CPT Code 0105U has been initiated under the Molecular Diagnostics Services ("MolDx") programme. A Medicare coverage determination is expected in the first half of calendar year 2021.

Regulatory

I am pleased to report that both the US federal and state regulatory review processes for *KidneyIntelX*™ continue on track, in-line with our previous announcements. Engagement and progress with the US Food and Drug Administration on its review of *KidneyIntelX*™ under the Breakthrough Device designation granted in May 2019 continues in line with our expectations.

In January 2020, we announced that our newly established commercial laboratory operation in Salt Lake City, Utah received a Clinical Laboratory Improvement Amendments ("CLIA") Certificate of Registration, allowing the laboratory to begin patient testing effective immediately. The Salt Lake City laboratory facility supports the delivery of multiple elements in the Company's 2020 commercial strategy plan, including the scaling-up of test volumes, optimising sample processing costs and helping to accelerate payor coverage determinations.

Following receipt of the CLIA Certificate of Registration we are now beginning the process of requesting a Local Coverage Determination ("LCD") from Noridian Healthcare Solutions, the regional Medicare Administrative Contractor ("MAC") responsible for services performed in laboratories located in the State of Utah. Once submitted, review of the LCD request is expected to take approximately 12 months and once granted it applies to payment for *KidneyIntelX*™ tests run in any laboratory located in the regions that follow MolDx determinations, including the Utah laboratory regardless of where the sample is collected in the United States. Such a determination would be in addition to both coverage determination policies already adopted by insurance payor CDPHP and any further coverage determinations the Company may secure from public and private insurance payors during 2020 and beyond.

As previously announced, five states require a separate out-of-state license before RenalytixAI can provide testing services for their residents: California, Maryland, New York, Pennsylvania and Rhode Island. RenalytixAI initiated the application process with New York in December 2019. The initial in-person review of the *KidneyIntelX*™ testing service, looking at supporting laboratory systems and processes, was completed by the New York State Department of Health in January 2020. We intend to initiate the application process for the remaining four states in the first half of calendar year 2020.

Patient studies

We have now completed our expanded multi-centre clinical validation study for patients with DKD with positive results consistent with the *KidneyIntelX*™ interim results announced on 9 July 2019. These study results were submitted for peer-reviewed publication in February 2020 and are expected to be published in the second quarter of calendar year 2020.

During the period, a collaboration study was completed with University Medical Center Groningen ("UMCG"), Netherlands, to determine how effectively *KidneyIntelX*™ identifies those patients experiencing rapid kidney function decline and patients who eventually progressed to kidney failure and/or dialysis. The study included 3,500 patients across multiple time points with over 9,000 samples analysed. The findings are currently being evaluated and are expected to be submitted for presentation at the American Society of Nephrology Kidney Week, October 2020 in Denver, Colorado https://www.asn-online.org/education/kidneyweek/.

Due to earlier insurance payor and healthcare system interest than initially expected, we are now in the process of redesigning the planned *KidneyIntelX*™ utility study away from the 5,000 patient configuration originally envisaged at the time of our AIM admission to a more focused study programme aimed at evaluating *KidneyIntelX*™ in specific patient populations, with payment coverage agreed under partnership arrangements. We now expect that the majority of the patient testing will be covered by insurance and other third-party funding. This approach is targeted to achieve wider coverage and reimbursement and is aligned with our partnership-based business model, but will also result in considerable cost savings for the Company.

Key leadership appointments
We continue to ensure that management and our Board contains the right mix of skills to help deliver commercial success for our *KidneyIntelX*™ programme with an emphasis on leading clinical input. In October 2019, we appointed Dr. Chirag Parikh, Director of the Division of Nephrology and the Ronald Peterson Professor of Medicine at the Johns Hopkins School of Medicine, and the Chairman of the Company's CKD Advisory Board, as an independent Non-Executive Director. In July 2019, we announced the executive management appointment of industry veteran Thomas McLain as President and Chief Commercial Officer.

In addition, we have moved steadily to fill key operating positions to support commercial roll-out at scale, including hiring a Vice President of Market Access (commercial insurance reimbursement), a Head of Clinical Laboratory Operations, a Head of Product Management & Design, a Director of Clinical Trials, and a Director of Quality Assurance.

Intellectual Property
In the period, the US Patent and Trademark Office allowed claims extending the use of sTNFR1 (a blood-based biomarker) to all patients with diabetes to determine an increased risk of developing progressive kidney disease or kidney failure. Post period-end, we have also concluded further exclusive in-licensing to patent applications for core algorithms used in our *KidneyIntelX*™, a potentially first-in-class AI-IVD product.

We continue to build out our intellectual property portfolio and are actively evaluating in-licensing opportunities that will enhance our competitive product positioning.

FractalDx
The Company continues to evaluate its plans for *FractalDx* where it has identified two initial diagnostic products designed to address key unmet needs in kidney transplant. The first is a prognostic test performed prior to transplant to predict which transplant recipients are most at risk of acute rejection.. This test will be instrumental in guiding patient care including for immunosuppression therapy dosing to mitigate the toxic side effects and damage to the transplanted kidney due to excessive dosing. The second is a diagnostic test for evidence of rejection of the transplanted kidney in advance of any clinical symptoms. The results of this test can also provide valuable information on immune-suppression therapy and, notably, key information can be provided to a transplant clinician without the need for an invasive kidney biopsy, the analysis of which, using current techniques, misses approximately 20% of underlying rejections, which contribute to kidney injury and loss.

Improving transplant outcomes and post-transplant survival rates is also an important component of meeting objectives under the US Presidential Executive Order on *Advancing American Kidney Health*. Currently, 34% of kidney transplant recipients experience graft loss and rejection in the ten years post-transplant (source: *Hart et al., OPTN/SRTR 2019 Annual Data Report: Kidney*), which *FractalDx* products seek to reduce. Opportunities for the *FractalDx* portfolio continue to be assessed with input from our Transplant Advisory Board, chaired by Professor Barbara Murphy, MD, Murray M. Rosenberg Professor of Medicine, Chair of the Department of Medicine and Dean for Clinical Integration & Population Health at Mount Sinai Health Systems. The *FractalDx* products are supported by a significant body of clinical evidence, with key papers available at the following link:
https://renalytixai.com/investors/studies-supporting-utility-and-impact-of-fractaldx

The Board is currently considering options for a possible spin-out and admission to AIM of *FractalDX*. Such a spin-out transaction could provide the opportunity to secure separate financial resources for the *FractalDx* portfolio, with the goal of enabling accelerated development of *FractalDx* products and achievement of commercial milestones. A spin-out transaction could also allow RenalytixAI's shareholders to benefit from both the pure-play value of the *FractalDx* portfolio of transplant products and the standalone value of *KidneyIntelX*™ as it progresses through its own key milestones over the next 12 months and beyond.

These considerations are at an early stage and there can be no guarantee that any spin-out transaction will be completed. Further updates will be provided in due course, as appropriate.

Financial review
The results presented cover the six-month period from 1 July 2019 to 31 December 2019 ("H1 FY20"). The Group's presentational currency is the United States Dollar.

Income statement
Revenue
In H1 FY20, $0.1m in revenue was generated through the sale of assay materials in support of an unaffiliated study, of which $0.02m was booked as cost of goods sold, yielding a gross margin of just under $0.1m. The Group expects commercial testing sales to begin ramp-up in the second quarter of calendar year 2020.

Administrative costs
In H1 FY20, administrative expenses totalled $4.5m (H1 FY19: $2.9m). The major items of expenditure were general and administrative expenses of $4.2m (H1 FY19: $0.7m) which included $1.9m in employee-related costs and stock-based compensation, and $1.1m in subcontractors, legal, accounting, and other professional fees. Depreciation and amortization expense totalled $0.6m for the period. There was an offsetting foreign exchange gain of $0.1m. Figures from H1 FY19 for the above sub-categories were *de minimis* and therefore do not provide meaningful comparative data. Increases in labour, subcontractor and other expense reflect implementation of growth plans outlined during the Company's recent fundraising, and include development of laboratory operations and the hiring of key positions, including our president and chief commercial officer and head of product management and design control.

Finance income/costs
Finance income of $0.1m during H1 FY20 (H2 FY19: $0.02m expense) relates to interest earned on short-term investments.

Net loss
Net loss after tax during H1 FY20 of $3.8m (H2 FY19: $2.5m), is in line with expectations. Excluding share-based payments, depreciation, amortisation and deferred tax, H1 FY20 net loss was $3.2m (H2 FY19: $2.0m).

Balance sheet
At 31 December 2019, the Company held $42.5m in total assets (31 December 2018: $31.3m), and shareholders' equity totalled $41.2m (31 December 2018: $30.5m).

Inventory

During the period, the Company purchased $0.4m of consumable assay materials to be used in the processing of tests to be sold (no inventory on hand prior to the interim period).

Fixed assets
$0.5m in laboratory equipment was added during the period. At 31 December 2019, the Company held $0.7m in net book value of equipment (31 December 2018: $0.4m).

Intangible assets
$18.8m net book value of intangible assets held at 31 December 2019 (31 December 2018: $17.2m) includes payments made primarily to Mount Sinai for license and patent costs for the intellectual property underlying *KidneyIntelX*™, as well as assays pertaining to kidney transplant, amounts capitalised as development costs, and also intangible assets representing the value of the biomarker business purchased (in exchange for ordinary shares in the Company) from EKF.

Deferred tax
At 31 December 2019, a deferred tax asset of $1.6m had been estimated (31 December 2018: $0.4m) based on the accumulated tax losses in the US.

Cash and equivalents
The Group had cash on hand at 31 December 2019 of $20.8m (31 December 2018: $13.1m). Cash and equivalents are held in several deposit accounts in the US ($9.4m) and UK ($3.5m), as well as in US Treasury Bills ($7.9m) at 31 December 2019. Our expenditure plans remain sufficiently adaptable to align with available resources.

Borrowings
The Group has no long-term debt outstanding at 31 December 2019.

Capitalisation
In July 2019, the Company completed a follow-on placing of new ordinary shares, raising net proceeds of $16.1m after fees and related charges. The Company was admitted to trading on AIM in November 2018 and completed an associated equity financing of $26.8m net of fees and related charges.

Future developments and outlook
Ahead of our expected commercial launch into the Mount Sinai Health System in the second quarter of calendar year 2020, we have now initiated the final phase of deep integration with Mount Sinai's outpatient EMR. The *KidneyIntelX*™ live software integration into the Mount Sinai EMR is expected to be complete in the first quarter of calendar year 2020, with full deployment to enable seamless test ordering, secure data extraction and integration of reports back into the EMR expected ahead of anticipated launch. Live *KidneyIntelX*™ EMR integration will uniquely enable large volumes of patient data to be securely extracted and combined with biomarker results for processing by the *KidneyIntelX*™ machine-learning algorithm. Subsequent billable risk-score reporting will now be enabled for electronic transmission through the EMR back to treating clinicians to potentially improve care processes and help improve patient outcomes.

Live integration with a major healthcare system such as Mount Sinai is a core part of our business-to-business market strategy and allows *KidneyIntelX*™ to be deployed to larger scale populations of patients in a concentrated effort of human and capital resources. Most importantly, our business-to-business integrated partnership model creates the foundation for a long-term commercial relationship that leverages *KidneyIntelX*™ to provide appropriate clinical support to target populations through the course initial risk assessment, care pathway optimization, escalation of treatment and long-term management.

We believe successful implementation with Mount Sinai will help validate our business model approach to combating kidney disease that can be replicated in large population medical centers across the United States and into the United Kingdom, Europe and other territories throughout the world. In 2020, we are continuing to extend our commercial discussions with additional large healthcare providers, insurance payors and strategic partners for

further deployment of *KidneyIntelX*™ to provide precision medicine stratification for at-risk DKD populations in the United States.

We continue to believe that the macro environment for kidney disease has undergone disruptive positive change in the past year. Our own market-based experience has suggested an increasing level of urgency from large medical stakeholders to improve diagnosis and prognosis in earlier stages of kidney disease (stages 1, 2 and 3) for better health economics and patient outcomes.

The Executive Order signed by the President of the United States of America in July 2019, *Advancing American Kidney Health*, marked the launch of a new initiative to improve the lives of Americans suffering from kidney disease and outlined the magnitude of the problem, underscoring the significant need for our solutions. As stated in the order, "*Approximately 37 million Americans have chronic kidney disease and more than 726,000 have ESRD (end-stage renal disease). More than 100,000 Americans begin dialysis each year to treat ESRD. Twenty percent die within a year; fifty percent die within 5 years. Currently, nearly 100,000 Americans are on the waiting list to receive a kidney transplant.*"

We remain confident that our strategic approach and technology are positioned to bring the predictive power of artificial intelligence and precision diagnostics to the war on kidney disease to improve patients' lives and control health care costs globally.

Julian Baines
Non-Executive Chairman

3 March 2020

CONSOLIDATED INCOME STATEMENT
FOR THE 6 MONTHS ENDED 31 DECEMBER 2019

		Unaudited 6 months ended 31 December 2019 $'000	Unaudited 6 months ended 31 December 2018 $'000	Audited Period ended 30 June 2019 $'000
Revenue		**105**	-	-
Cost of sales		**(20)**	-	-
Gross profit		**85**	-	-
Administrative expenses		**(4,548)**	(2,863)	(6,955)
Operating loss		**(4,463)**	(2,863)	(6,955)
Net finance income/(cost)		**70**	(20)	19
Loss before tax		**(4,393)**	(2,883)	(6,936)
Taxation	Note 4	**626**	366	959
Loss for the period		**(3,767)**	(2,517)	(5,977)

		Unaudited 6 months ended 31 December 2019 $	Unaudited 6 months ended 31 December 2018 $	Audited Period ended 30 June 2019 $
Loss per Ordinary share from continuing operations				
Basic and diluted	Note 5	**(0.06)**	(0.09)	(0.16)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME
FOR THE 6 MONTHS ENDED 31 DECEMBER 2019

	Unaudited 6 months ended 31 December 2019 $'000	Unaudited 6 months ended 31 December 2018 $'000	Audited Period ended 30 June 2019 $'000
Loss for the period - continuing operations	**(3,767)**	(2,517)	(5,977)
Other comprehensive income:			
Items that may be subsequently reclassified to profit or loss			
Current translation differences	**1**	(111)	(595)
Other comprehensive loss for the period	**1**	(111)	(595)
Total comprehensive loss for the period	**(3,766)**	(2,628)	(6,572)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT 31 DECEMBER 2019

	Notes	**Unaudited as at 31 December 2019 $'000**	Unaudited as at 31 December 2018 $'000	Audited as at 30 June 2019 $'000
Assets				
Non-current assets				
Property, plant and equipment	6	**722**	410	278
Intangible assets	7	**18,755**	17,236	18,287
Deferred tax assets		**1,585**	433	959
Total non-current assets		**21,062**	18,079	19,524
Current Assets				
Security deposits		**76**	-	49
Trade and other receivables		**-**	59	-
Inventory		**435**	-	-
Prepaid and other current assets		**115**	107	61
Cash and cash equivalents		**20,792**	13,095	9,288
Total current assets		**21,418**	13,261	9,398
Total assets		**42,480**	31,340	28,922
Equity attributable to owners of the parent				
Share capital		**192**	171	175
Share premium		**50,138**	33,247	34,032
Share-based payment reserve		**1,184**	88	532
Foreign currency reserves		**(594)**	(98)	(595)
Retained earnings		**(9,744)**	(2,877)	(5,977)
Total equity		**41,176**	30,531	28,167
Liabilities				
Current liabilities				
Trade and other payables		**1,304**	809	755
Total liabilities		**1,304**	809	755
Total equity and liabilities		**42,480**	31,340	28,922

CONSOLIDATED STATEMENT OF CASH FLOWS
FOR THE 6 MONTHS ENDED 31 DECEMBER 2019

	Unaudited 6 months ended 31 December 2019 $'000	Unaudited 6 months ended 31 December 2018 $'000	Audited as period ended June 2019 $'000
Cash flow from operating activities			
Loss before income tax	**(4,393)**	(2,883)	(6,936)
Adjustments for			
-Depreciation	**27**	15	31
-Amortisation and impairment charges	**524**	810	1,094
-Net finance (income)/costs	**(70)**	20	-
-Share-based payments	**652**	88	532
Changes in working capital			
-Trade and other receivables	**-**	(41)	218
-Inventory	**(435)**	-	-
-Prepaid assets and other current assets	**(54)**	(107)	(61)
-Security deposits	**(27)**	-	(49)
-Trade and other payables	**550**	688	755
Cash used in operations	**(3,226)**	(1,410)	(4,416)
Interest received/(paid)	**70**	(20)	-
Net cash used in operating activities	**(3,156)**	(1,430)	(4,416)
Cash flow from investing activities			
Purchase of property, plant and equipment (PPE)	**(471)**	(425)	(308)
Purchase of intangibles	**(992)**	(11,476)	(12,741)
Net cash used in investing activities	**(1,463)**	(11,901)	(13,049)
Cash flow from financing activities			
Issue of shares (net of issue costs)	**16,123**	26,782	26,753
Proceeds from loans	**-**	-	438
Repayment of loans	**-**	(438)	(438)
Net cash generated from financing activities	**16,123**	26,344	26,753
Net increase in cash and cash equivalents	**11,504**	13,013	9,288
Cash and cash equivalents at beginning of period	**9,288**	82	-
Cash and cash equivalents at end period	**20,792**	13,095	9,288

Substantial non-cash items include the acquisition of the intangible assets in return for the issue of Ordinary shares, applicable to the period ended 30 June 2019, and amortisation of intangible assets.

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
FOR THE 6 MONTHS ENDED 31 DECEMBER 2019

	Share Capital $'000	Share Premium $'000	Share-based payment reserve $'000	Foreign Currency Reserve $'000	Retained earnings $'000	Total equity $'000
At 1 July 2018	**66**	**-**	**-**	**13**	**(360)**	**(281)**
Comprehensive income						
Loss for the period	-	-	-	-	(2,517)	**(2,517)**
Other comprehensive income						
Currency translation differences	-	-	-	(111)	-	**(111)**
Total comprehensive income	**-**	**-**	**-**	**(111)**	**(2,517)**	**(2,628)**
Transactions with owners						
Issue of shares	105	34,730	-	-	-	**34,835**
Less issue costs	-	(1,483)	-	-	-	**(1,483)**
Share-based payments	-	-	88	-	-	**88**
Total contributions by owners	**105**	**33,247**	**88**	**-**	**-**	**33,440**
At 31 December 2018	**171**	**33,247**	**88**	**(98)**	**(2,877)**	**30,531**
Comprehensive income						
Loss for the period	-	-	-	-	(3,100)	**(3,100)**
Other comprehensive income						
Currency translation differences	-	-	-	(497)	-	**(497)**
Total comprehensive income	**-**	**-**	**-**	**(497)**	**(3,100)**	**(3,597)**
Transactions with owners						
Issue of shares	4	792	-	-	-	**796**
Less issue costs	-	(7)	-	-	-	**(7)**
Share-based payments	-	-	444	-	-	**444**
Total contributions by owners	**4**	**785**	**444**	**-**	**-**	**1,233**
At 30 June 2019	**175**	**34,032**	**532**	**(595)**	**(5,977)**	**28,167**
Comprehensive income						
Loss for the period	-	-	-	-	(3,767)	**(3,767)**
Other comprehensive income						
Currency translation differences	-	-	-	1	-	1
Total comprehensive income	**-**	**-**	**-**	**1**	**(3,767)**	**(3,766)**
Transactions with owners						
Issue of shares	17	17,090	-	-	-	17,107
Less issue costs	-	(984)	-	-	-	(984)
Share-based payments	-	-	652	-	-	652
Total contributions by owners	**17**	**16,106**	**652**	**-**	**-**	**16,775**
At 31 December 2019	**192**	**50,138**	**1,184**	**(594)**	**(9,744)**	**41,176**

NOTES FORMING PART OF THE INTERIM FINANCIAL STATEMENTS

1. General information and basis of presentation

Renalytix AI plc is a public limited company incorporated in the United Kingdom (Registration Number **11257655**). The address of the registered office is Avon House, 19 Stanwell Road, Penarth, CF64 2EZ. The Company's shares are traded on the AIM market of the London Stock Exchange.

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 information in these interim results is that of the holding company and its subsidiary. It has been prepared in accordance with the recognition and measurement requirements of International Financial Reporting Standards as adopted for use in the EU (IFRSs), IFRS IC interpretations, and the Companies Act 2006 applicable to companies reporting under IFRS. The accounting policies applied by the Group in this financial information are the same as those applied by the Group in its financial statements for the period ended 30 June 2019 and which will form the basis of the 2019/20 financial statements except for a number of new and amended standards which have become effective since the beginning of the previous financial year. These new and amended standards are not expected to materially affect the Group.

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.

The financial information presented herein does not constitute full statutory accounts under Section 434 of the Companies Act 2006 and was not subject to a formal review by the auditors. The financial information in respect of the period ended 30 June 2019 has been extracted from the statutory accounts which have been delivered to the Registrar of Companies. The Group's Independent Auditor's report on those accounts was unqualified, did not include references to any matters to which the auditor drew attention by way of emphasis without qualifying their report and did not contain a statement under section 498(2) or 498(3) of the Companies Act 2006. The financial information for the half years ended 31 December 2019 and 31 December 2018 is unaudited and the period to 30 June 2019 is audited.

These interim accounts have not been prepared in accordance with IAS 34.

2. Significant accounting policies

Going concern

The Group meets its 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 interim 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 should be able to operate within the level of its current funding arrangements.

The Directors believe that the Company and the Group 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. Subsidiaries are all entities over which the Group has the power to govern their financial and operating policies generally accompanying a shareholding of more than fifty per cent of the voting rights. 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 an acquisition by acquisition basis, the Group recognises any non-controlling interest in the acquiree either at fair value or at the non-controlling interest's proportionate share of the acquiree's net assets.

The excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition date fair value of any previous equity interest in the acquiree over the fair value of the Group's share of the identifiable net assets acquired is recorded as goodwill. If this is less than the fair value of the net assets of the subsidiary acquired in the case of a bargain purchase, the difference is recognised directly in the income statement.

Inter-Company transactions, balances and unrealised gains on transactions between Group companies are eliminated. Unrealised gains and 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.

Goodwill and fair value adjustments arising on the acquisition of a foreign entity are treated as assets and liabilities of the foreign entity and translated at the closing rate.

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:

Plant and machinery 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 to 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.

Inventories

Inventories and work in progress are stated at the lower of cost and net realisable value. Cost is calculated on a first in and first out basis and includes direct costs and attributable overheads, where appropriate. Net realisable value represents the estimated selling price less all estimated costs of completion and applicable selling costs. Where necessary, provision is made for slow-moving and obsolete inventory. Inventory on consignment and their related obligations are recognised in current assets and payables respectively.

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 consolidated cash flow statement, cash and cash equivalents consist of cash and short-term deposits as defined above.

Share capital

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.

Revenue

Revenue is accounted for in accordance with the principles of IFRS 15.

Revenue for the sale of goods is measured at the fair value of the consideration received or receivable and represents the invoiced value for the sale of the goods net of sales taxes, rebates and discounts. Revenue from the sale of goods is recognised when control of the products has transferred which is when a Group company has delivered products to the customer, the customer has accepted delivery of the products and collectability of the related receivables is reasonably assured. A receivable is recognised when the goods are delivered as this is the point in time that the consideration is unconditional because only the passage of time is required before the payment is due. Where contracts contain multiple deliverables, and the volume of each deliverable can be determined with reasonable certainty, then the transaction price will be allocated to each performance obligation based on the expected cost of each item.

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.

3. Segmental reporting

The Group operates as a single segment.

4. Income tax

	Unaudited 6 months ended 31 December 2019 $'000	Unaudited 6 months ended 31 December 2018 $'000	Audited Period Ended 30 June 2019 $'000
Deferred tax			
Tax losses	**626**	366	959
Total deferred tax	**626**	366	959
Income tax credit	**626**	366	959

5. 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 share in issue during the period.

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.

	Unaudited 6 months ended 31 December 2019 $'000	**Unaudited 6 months ended 31 December 2018 $'000**	**Audited Period ended 30 June 2019 $'000**
Loss attributable to owners of the parent	**(3,767)**	(2,517)	(5,977)
Weighted average number of ordinary share in issue	**58,563,960**	27,487,006	37,332,983
	Cents	Cents	Cents
Basic and diluted Loss per share	**(0.06)**	(0.09)	(0.16)

6. Property, plant and equipment

Group	**Fixtures and fittings $'000**
Cost	
At the beginning of period	**-**
Additions	**425**
At 31 December 2018	**425**
Transfer to intangible assets	(116)
At 30 June 2019	**309**
Additions	471
At 31 December 2019	**780**
Depreciation	
At beginning of period	-
Charge for the period	15
At 31 December 2018	**15**
Charge for the period	16
At 30 June 2019	**31**
Charge for the period	27
At 31 December 2019	**58**
Net book value	
31 December 2019	**722**
30 June 2019	**278**
31 December 2018	**410**

7. Intangible Assets

Group

	Trademarks trade names & licenses $'000	Trade secrets $'000	Develop-ment costs $'000	Total $'000
Cost				
At the beginning of period	**-**	-	-	-
Additions	**10,979**	6,570	497	18,046
At 31 December 2018	**10,979**	6,570	497	18,046
Additions	**18**	74	1,243	1,335
Foreign translation	**5**	(3)	-	2
At 30 June 2019	**11,002**	6,641	1,740	19,383
Additions	**-**	-	992	992
At 31 December 2019	**11,002**	6,641	2,732	20,375
Amortisation				
At beginning of period	**-**	-	-	-
Charge for the period	**810**	-	-	810
At 31 December 2018	**810**	-	-	810
Charge for the period	**285**	-	-	285
Foreign translation	**1**	-	-	1
At 30 June 2019	**1,096**	-	-	1,096
Charge for the period	**524**	-	-	524
At 31 December 2019	**1,620**	-	-	1,620
Net book value				
31 December 2019	**9,382**	6,641	2,732	18,755
30 June 2019	**9,906**	6,641	1,740	18,287
31 December 2018	**10,169**	6,570	497	17,236

8. Dividends

No dividends to shareholders of the holding company were provided or paid during the six months to 31 December 2019 (six months to 31 December 2018 and period to 30 June 2019: both nil). 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.