Final results

September 3, 2019

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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*^{TM} 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*^{TM} 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."

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