

RENALYTIX AI

Half-year Report

March 3, 2020

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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."*

Enquiries

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About Kidney Disease

Kidney disease is now recognised as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control estimates there that 15% of United States adults or 37 million people currently have kidney disease. It is reported that 9 out of 10 adults with chronic kidney disease 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 die in the United States while waiting for a kidney transplant.

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

About RenalytixAI

RenalytixAI is a developer of artificial intelligence-enabled clinical *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, patient stratification for drug clinical trials, and drug target discovery. For more information, visit renalytixai.com