

# RENALYTIX AI

## Half-year Report

March 25, 2019

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Renalytix AI plc (AIM: RENX), the AIM quoted developer of artificial intelligence-enabled diagnostics for kidney disease, announces its inaugural unaudited interim results for the six months ended 31 December 2018.

### Operational highlights

- Secured agreements for *KidneyIntelIX™* clinical validation patient sample access with participating institutions (University of Pennsylvania, Emory University, and the Icahn School of Medicine at Mount Sinai ("Mount Sinai"))
- Established investigator network for *KidneyIntelIX™* trial design and data review, with experts from Harvard, Mount Sinai, the James J. Peters VA Medical Center, Johns Hopkins, Wake Forest Baptist Health, Northwestern University and others
- Submitted a request to the Food and Drug Administration ("FDA") for Breakthrough Device Designation for *KidneyIntelIX™*
- Submitted a request to the Centers for Medicare & Medicaid Services ("CMS") for a parallel reimbursement and regulatory review process
- Shipped first production lot of multiplex plates from *in vitro* diagnostics manufacturer Meso Scale Diagnostics to the Company's New York and Georgia laboratories
- Executed exclusive license with Mount Sinai for *FractaIDx* portfolio of technologies in the field of kidney transplant rejection

### Financial highlights

- Completed net capital financing of c. \$27m and started trading on AIM on 6 November 2018
- Nearly \$1.4m capital investment to date in artificial intelligence (AI) technology and clinical assay development
- Net loss after tax of \$2.5m for the interim period
- Cash on hand of \$13.1m as of 31 December 2018

### Post-period end

- Initiation of a c. 5,000 sample clinical validation study for the Company's lead AI-enabled diagnostic solution, *KidneyIntelIX™* with results anticipated in mid-2019
- Expansion of leadership team with the appointment of Patricia Connolly as vice president of clinical and scientific affairs, Paul Brenner, Ph.D., Associate Director of Notre Dame's Center for Research Computing, as data security advisor
- Joint venture agreement with AKESOGen, an industry-leading commercial laboratory facility and provider of clinical trial precision medicine services located in Atlanta, Georgia, that expands operational testing capacity
- Confirmation study in c. 870 patients expected to be published in the coming days

As these are the inaugural interim accounts for the Group, no comparative information is presented.

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

*"We are pleased with the rate of progress that we have made since IPO and are confident that we will continue to deliver key operational milestones in accordance with our plans. Our immediate strategy is focused on product development, regulatory authority engagement and the pathway to payer reimbursement in the United States, with each such milestone having the potential to create significant value for the Company."*

*"Our lead programme for detection of fast-progressing kidney disease, KidneyIntelIX™, is expected to launch in the second half of this calendar year 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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### Enquiries

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