# **INVESTOR BRIEFING**

MARCH 25, 2019

### ARTIFICIAL INTELLIGENCE FOR KIDNEY DISEASE

RENALITIXA

CONFIDENTIAL

#### Agenda

Welcome – Julian Baines, Non-Executive Chairman, RenalytixAI

**Operational and financial highlights** – James McCullough, Chief Executive Officer, RenalytixAl

**The big problem in kidney disease and our solution** – Steven Coca, M.D. Member of the RenalytixAl Scientific Advisory Board

#### The impact of AI in kidney diagnostic medicine

- Dr. Steve Coca -Associate Professor, Medicine, Nephrology; Associate Chair for Clinical and Translational Research, Icahn School of Medicine at Mount Sinai
- Dr. Fergus Flemming Chief Technology Officer, RenalytixAl
- Dr. Erik Lium Executive Vice President, Mount Sinai Innovation Partners, Mount Sinai Health System and Non-Executive Director, RenalytixAI
- Rahul Patel Executive Vice President, Digital Product and Services, Persistent Systems

#### **Operational highlights**

*KidneyIntelX*<sup>™</sup> agreements secured for clinical validation patient sample access 



*KidneyIntelX*<sup>™</sup> investigator network 





KidneyIntelX<sup>™</sup> first production lot from Meso Scale Diagnostics for blood biomarkers shipped 



~5,000 patient clinical validation study initiated with read-out expect this summer 



#### **Operational highlights continued**

- Submitted request to Food and Drug Administration ("FDA") for Breakthrough Device Designation for KidneyIntelX<sup>TM</sup>
- Submitted request to Centers for Medicare & Medicaid Services ("CMS") for parallel reimbursement and regulatory review
- Joint-venture agreement completed with AKESOgen, Inc for expanded testing capability



Advancing machine learning technology platform with Persistent Systems



Exclusive license executed with Mount Sinai for *FractalDx* portfolio of technologies in the field of kidney transplant rejection



#### **Financial highlights**

- Completed net capital financing of c. \$27m and associated AIM admission on November 6, 2018
- In-licensed IP underlying two product technologies for \$11.0m in upfront payments
- Nearly \$1.4m capital investment to date in AI technology platform and clinical assay development
- Net loss *after tax* of \$2.5m for the interim period
- Cash as of December 31, 2018 of \$13.1m



#### The big problem in kidney disease and our solution

#### Steven Coca, M.D.

Associate Professor, Medicine, Nephrology; Associate Chair for Clinical and Translational Research, Icahn School of Medicine at Mount Sinai

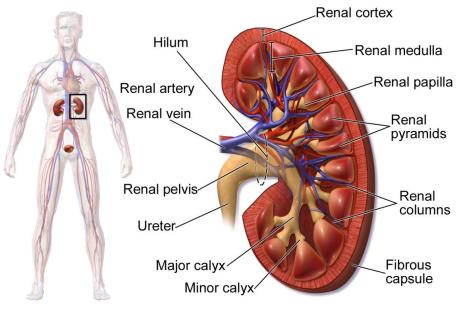
**Fergus Flemming** 

Chief Technology Officer, RenalytixAI

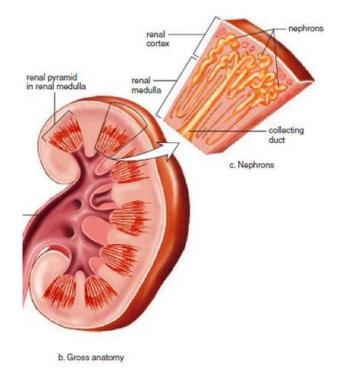


#### What are the kidneys?

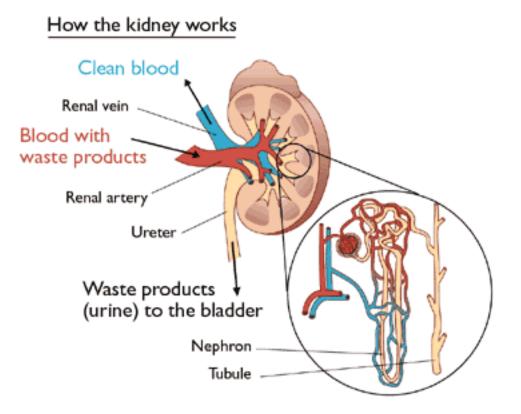
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**Kidney Anatomy** 

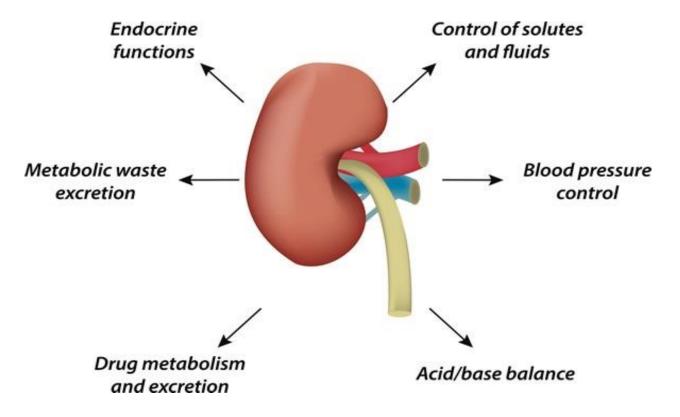


#### What do the kidneys do?

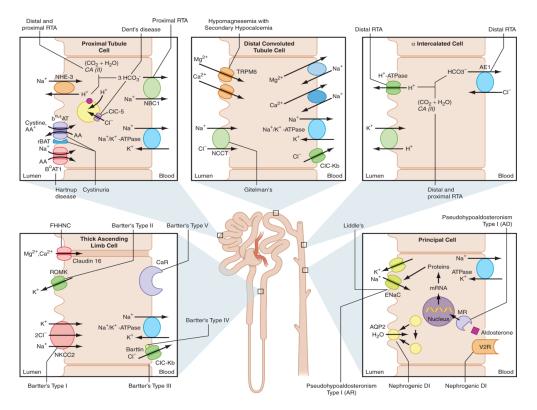




#### A number of major body functions start here

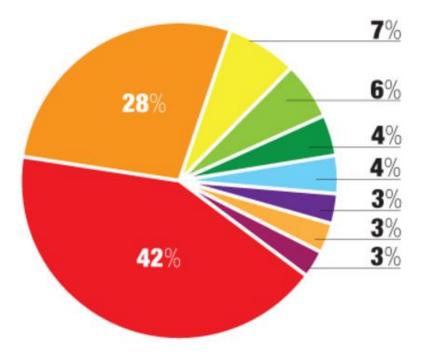


# Functions basic to life include transport of electrolytes, amino acids, and water



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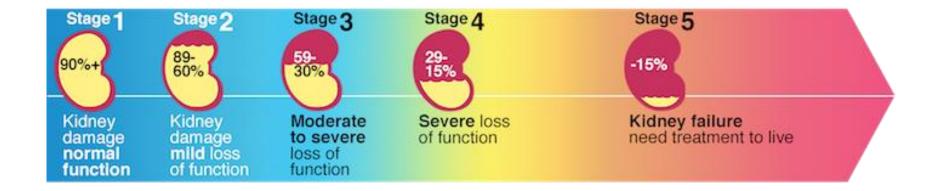
#### Top causes of chronic kidney disease



Type 2 diabetes High blood pressure Glomerular diseases Miscellaneous Unknown Type 1 diabetes Cystic/Hereditary Nephritis Tumors

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#### **Stages of chronic kidney disease**



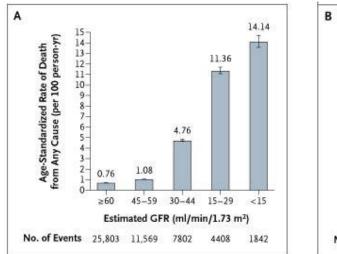


#### So goes kidney function so goes...

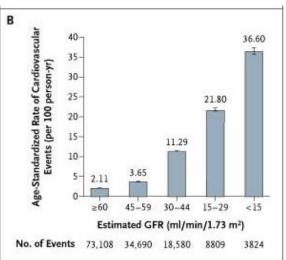
Death

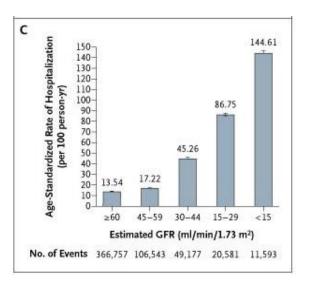
#### **Cardiovascular Events**

#### Hospitalizations

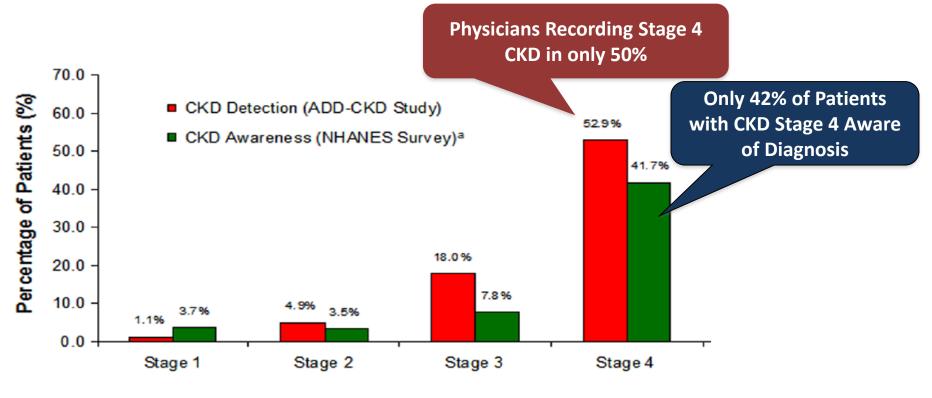


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#### Doctors don't have the tools - patients are in the dark

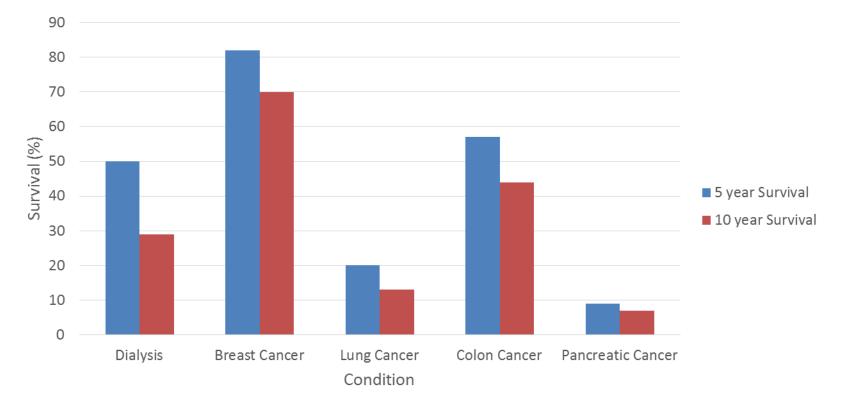


CKD Stage

KENALI IIX A

Szczech LA, et al. Plos One 2014

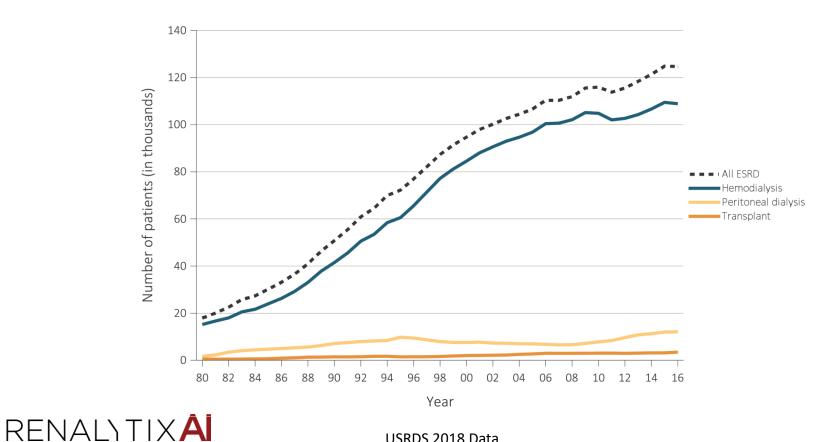
#### Survival on dialysis is lower than several cancers



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Naylor KL, et al. AJKD 2019 (online first)

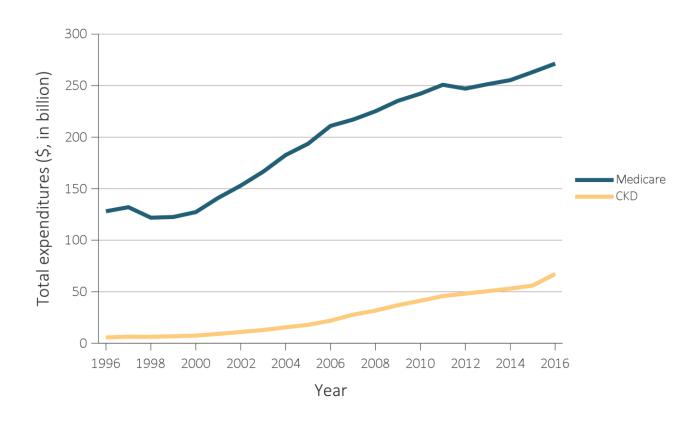
#### New cases of kidney failure continues to grow each year



USRDS 2018 Data

#### **Costs are unsustainable!**

20% of US government medical budget



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USRDS 2018 Data

# We need advanced diagnostic technology now to identify fast-progressing kidney disease



#### **The Solution**

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#### Kind Attention

This is to bring to your notice that your Provider Admin is changed from "Adam Johnson" to James Cameroon with effective from 17th0CT2018. For any further queries please reach out at superadmin@kindneyintelx.com

Super Admin | Sept 27, 2018

#### New Provider Assignment

This is to bring to your notice that you have a new Provider Mount Sinai added to your providers list managed by you. For any further queries please reach out at superadmin@kindneyintelx.com

Super Admin | Sept 27, 2018

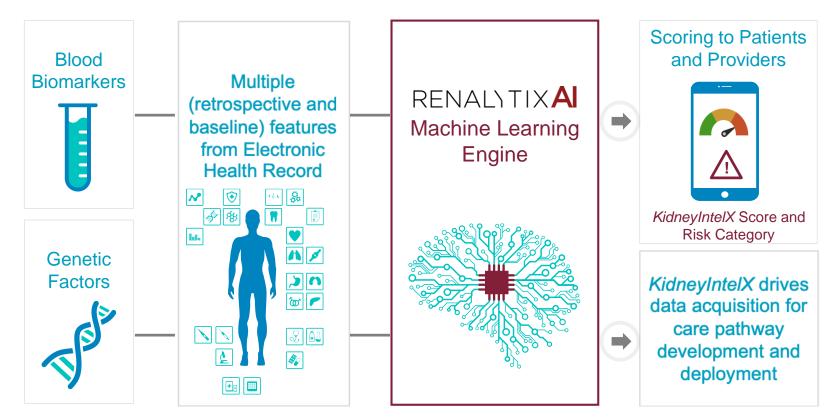
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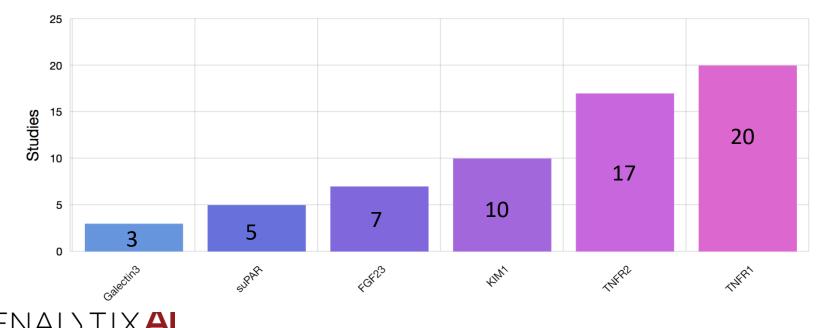
#### KidneyIntelX combines disparate data sources for better prediction



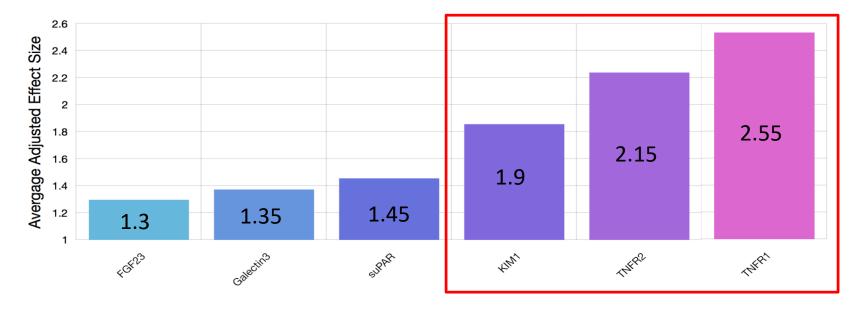
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# *KidneyIntelX* blood biomarkers sTNFR1, sTNFR2 and KIM-1 are the strongest with the most published evidence

**#Published Studies for Each Plasma Biomarker** 



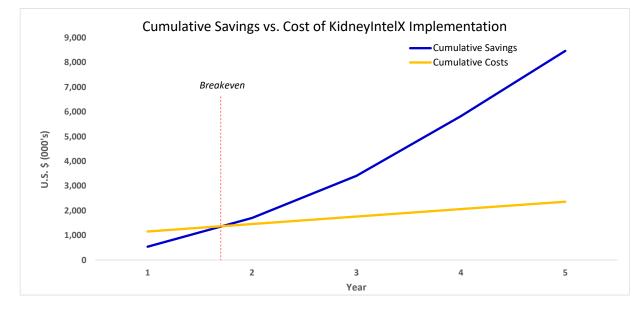
# *KidneyIntelX* blood biomarkers pooled adjusted hazard ratio for chronic kidney disease outcomes



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#### Increased diagnostic performance can translate into major cost savings

#### > \$4.0M in savings per 1,000 patients tested



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#### Key Model Assumptions

- 1,000 patients tested
- \$760 cost per KidneyIntelX test plus \$100 implementation cost
- KidneyIntelX tested population: 46.5% CKD stage 3, 53.5% stages 1-2 (UA 2,3)
- % of pre-CKD stage 3 patients with albuminuria (UA 2 & 3) = 28%
- Savings measured over first five years only @ 10% discount rate
- Preventative measures (cost of \$1-3K/yr. depending on CKD stage per patient) applied to top 20% of high risk patients
- Care cost per patient ranges from \$11K (no advanced CKD) to \$87K (ESRD pre-dialysis). Dialysis cost of \$88K; transplant \$262K

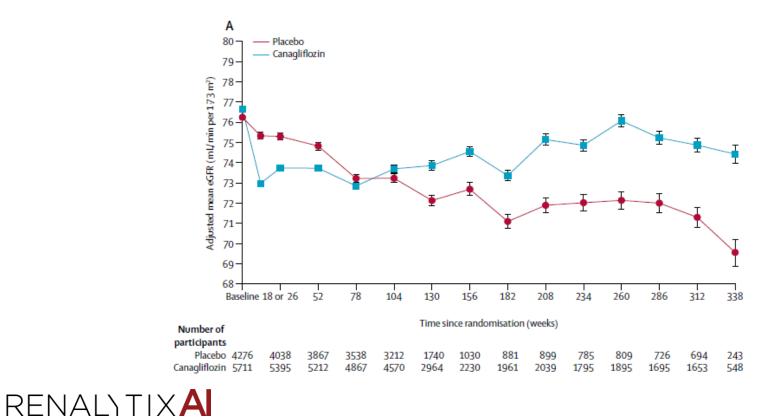
## Advanced Diagnostics + Novel Drug Development = Personalized Medicine

### We've done it in cancer

## Now its time for the kidney



# The age of personalized drug therapy for kidney is here (SGLT2 Inhibitors)



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#### **Discussion – the impact of AI in kidney diagnostic medicine**

**Steven Coca, MD** - Associate Professor, Medicine, Nephrology; Associate Chair for Clinical and Translational Research, Icahn School of Medicine at Mount Sinai

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**Dr. Erik Lium, PhD** - Executive Vice President, Mount Sinai Innovation Partners, Mount Sinai Health System and Non-Executive Director, RenalytixAl

Rahul Patel - Executive Vice President, Digital Product and Services, Persistent Systems

John Quackenbush, PhD - Professor, Biostatistics, Harvard T.H. Chan School Of Public Health, Professor, Biostatistics and Computational Biology, Dana-Farber Cancer Institute, member of the RenalytixAl Scientific Advisory Board

