

RENALYTIX **AI**TM

Renalytix AI

Company Overview

JP Morgan Conference
January 2021



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The Presentation also contains estimates, projections and other information concerning our industry, our business and the markets for KidneyIntelX and any other products we may develop in the future. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in the information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research as well as from reports, research, surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this Presentation, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties and are subject to change based on various factors. Market data and industry information used throughout this Presentation are based on management's knowledge of the industry and the good faith estimates of management. We also relied, to the extent available, upon management's review of independent industry surveys and publications and other publicly available information prepared by a number of third-party sources. All of the market data and industry information used in this Presentation involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Although we believe these sources are reliable, we cannot guarantee the accuracy or completeness of this information, and we have not independently verified this information. While we believe that the estimated market position, market opportunity and market size information included in this Presentation are generally reliable, such information, which is derived in part from management's estimates and beliefs, are inherently uncertain and imprecise.

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Investment Highlights

FIRST in AI *in vitro* Diagnostics

- KidneyIntelX is first-in-class, clinical grade, artificial intelligence-enabled *in vitro* Dx
- First advanced prognostic in early-stage kidney disease (Stage 1, 2, 3), if approved by the FDA
- Granted FDA Breakthrough Device designation
- New York State Department of Health approved for commercial testing
- Commercial capable in 50 states
- Unique configuration real-time biology + EHR features + machine learning enabled algorithm

Growth Model with Core Partnerships

- System population health



- Integrated care models



- Payor driven



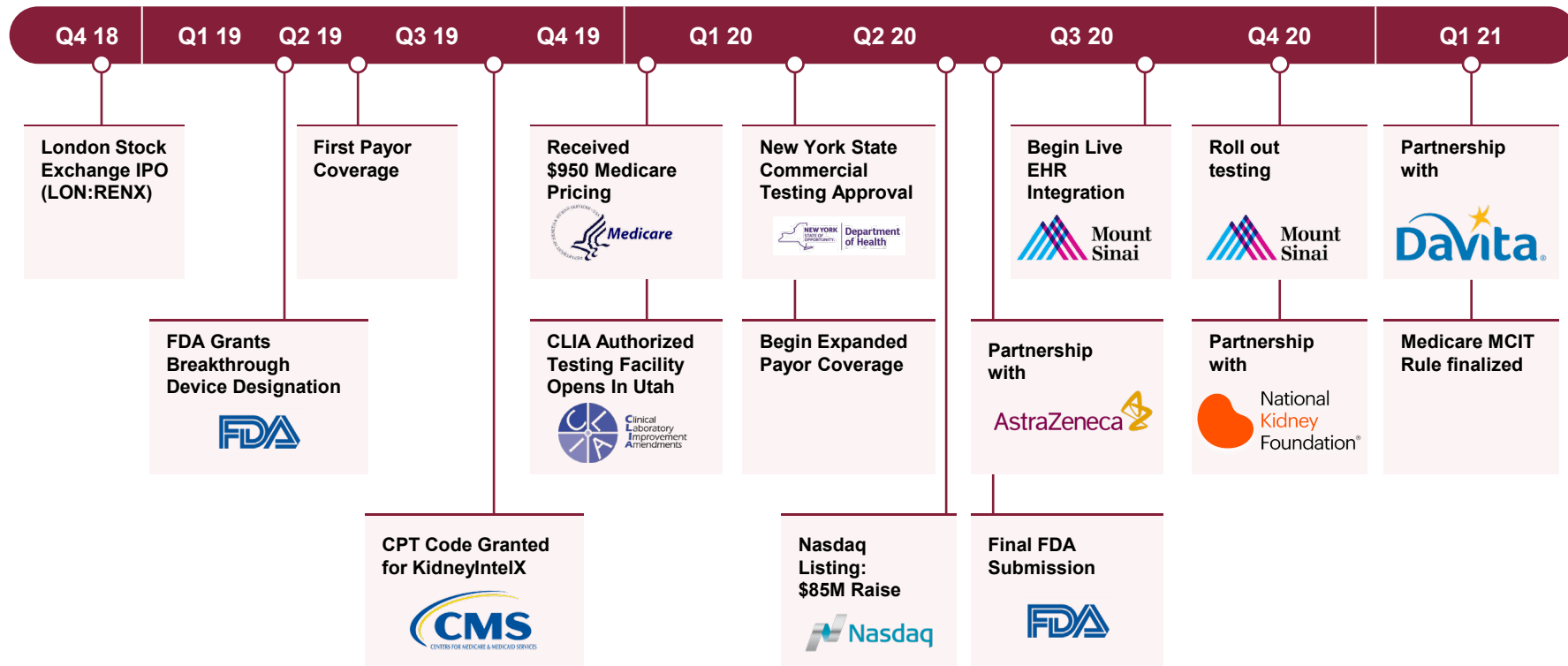
- Precision therapeutic care pathways



Anticipated Near-Term Major Events

- FDA clearance and national roll-out
- National Medicare coverage under MCIT
- Expanding use to broader disease populations to achieve TAM ~40M patients
- International markets regulatory review

Key Events Timeline



*Quarters based on calendar year

Unprecedented Size and Cost Drivers in Kidney Disease Market

The Numbers

37 million

Americans currently estimated with CKD

850 million

people estimated with CKD worldwide

>100,000

Americans begin hemodialysis from kidney failure / year

The Healthcare Challenge

~60 million

adults in the U.S. expected to be diagnosed with diabetes by 2060

100,000

Americans waiting for kidney transplant; 13 die every day

63%

of patients initiate dialysis in an unplanned fashion ("crash")

The Cost

>\$120 billion

or 20% of Medicare budget spent per year for treatment of CKD (incl. ESKD)

\$36 billion

or 6.7% of Medicare budget spent per year for treatment for kidney failure to care for <1% of the covered population

\$1.3 billion¹

can be saved over 5 years per 100,000 patients with DKD

KidneyIntelX
estimated TAM*
(Initial Indicated Use)
~\$12 billion

¹Based on one test per patient assuming Medicare national price of \$950 per reportable test. Source: McCullough, KP, et al. J Am Soc Nephrol. 2019;30:127–135

Urgent and Immediate Need to Clarify Who Has Progressive Kidney Disease

1 in 5

will rapidly progress
to kidney failure



**Who
Is It?**



Each of these patients has an **UACR between 30–299 mg/g**
and a **GFR of 45–59 ml/min/1.73m²**

KidneyIntelX Enables Precision Prognosis Anchored in Real-time Biology in Early-Stage Kidney Disease



Step 1 **Blood draw**

Precision
Biomarkers



Step 2 **Data extraction**

Patient records
historic + current



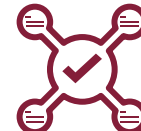
Step 3 **Algorithms**

Risk score
analysis



Step 4 **Reportable result**

Clinicians and
patients



Step 5 **Care navigation**

Optimized referrals
& treatment

Clear, Easily Understood Prognosis with Actionable Steps

KidneyIntelX™

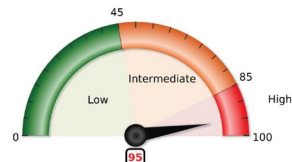
Test Report

Ordered by Dr. Fran Lake
Collection Date 8/14/2020
Report Date 8/19/2020
Specimen ID 665544

PATIENT INFORMATION

NAME	SEX	DATE OF BIRTH	MEDICAL RECORD #
Jane Lee	F	1/1/1960	00998877

RISK OF PROGRESSIVE DECLINE IN KIDNEY FUNCTION



95

Patients with a **high** KidneyIntelX score have an elevated risk of progressive decline in kidney function

The KidneyIntelX score ranges from 0-100 and correlates with the probability of progressive decline in kidney function in the study population. Risk classification is provided to guide interpretation of the risk score using cut-offs related to clinical outcomes.

SIGNED

DATE

TIME

Laboratory Director: Michael J. Donovan PhD, MD, CLIA, Renalix AL 101 6th Ave, 3rd Floor, Room 324 New York, NY 10013, CLIA Number: 3302156875

This test was developed and its performance characteristics determined by Renalix AI, Inc. It has not been cleared or approved by the FDA nor is it currently required to be. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. The test is used for clinical purposes. It should not be regarded as investigational or for research. See page 2 for further details.

EXAMPLE OF CLINICAL PATHWAY WITH KIDNEYINTELX

Frequency of Monitoring / Referral		Comprehensive Strategy to Maximize Protection for Diabetic Kidney Disease Progression and Cardiovascular Disease ^{1,2}	
Monitoring 3x/year	Nephrology Referral	Titrate ACEI or ARB to maximally tolerated dose	Strongly consider SGLT2 inhibitor therapy unless contraindicated

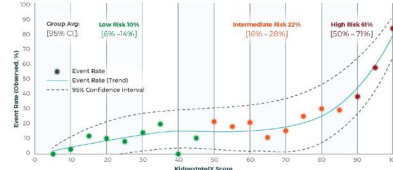
¹KIDIGO 2021 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease https://kdigo.org/wp-content/uploads/2021/02/KIDIGO_2021_CPG_Cupdf
²Executive Summary of the 2020 KDIGO Diabetes Management in CKD Guideline <https://kdigo.org/2020/05/20/>
³ADA guidelines https://care.diabetesjournals.org/content/63/Supplement_1/5333

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CLINICAL VALIDATION STUDY RESULTS

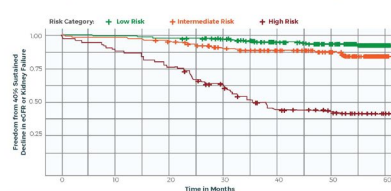
The KidneyIntelX test was validated in an analysis of 1146 patients with type 2 diabetes selected from two independent cohorts with chronic kidney disease status representative of patients in the intended use population. The model relating the KidneyIntelX score to progressive decline in kidney function up to 5 years in the validation study is displayed in Figures 1a and 1b below.

Figure 1a. KidneyIntelX Score and Event Rate of Progressive Decline in Kidney Function



In the clinical validation study, patients who had a **KidneyIntelX score > 85** were classified as **high risk**. The high risk patient group averaged a **61% probability of progressive decline in kidney function** up to 5 years compared to the low and intermediate risk groups that averaged a 10% and 22% probability, respectively.

Figure 1b. Kaplan-Meier Curves by KidneyIntelX Risk Strata for the Endpoint of Sustained 40% Decline in eGFR or Kidney Failure



Patients classified as **high risk by KidneyIntelX** experienced faster progression to end point of sustained 40% decline in eGFR or kidney failure. Separation of the Kaplan-Meier curve in the high-risk stratum occurred within the first year and progressively declined over time.

Ref: Chan L, et al. MedRxiv. 2020;06.01.20119321

ABOUT THE TEST

KidneyIntelX is a quantitative electrochemiluminescence immunoassay using the MESO SECTOR S 600 instrument for measurement of soluble Tumor Necrosis Factor Receptor 1 (sTNFR1), soluble Tumor Necrosis Factor Receptor 2 (sTNFR2) and Kidney Injury Molecule-1 (KIM-1) in human plasma combined with clinical data, using an artificial intelligence-derived algorithm to produce a composite risk score.

It is indicated for use as an aid to further assess the risk of progressive decline in kidney function within a period of up to 5 years in patients over the age of 21 with Type 2 diabetes and existing chronic kidney disease. Patients with chronic kidney disease will have an estimated glomerular filtration rate [eGFR] of 30-59 mL/min/1.73 m² [G3a, G3b] or an eGFR ≥ 60 with albuminuria [UACR] ≥ 30 mg/g [A2, A3].

A **progressive decline in kidney function** occurs when one or more of the following conditions are observed:

- Rapid Kidney Function Decline (RKFD) defined as an eGFR slope of ≥ 5 mL/min/1.73 m²/year
- Sustained decrease in eGFR ≥ 40% confirmed at least 3 months apart
- Kidney Failure, defined by sustained eGFR < 15 mL/min/1.73 m², initiation of long-term dialysis, or kidney transplantation.

*KDIGO 2021 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease
KidneyIntelX is not intended as a screening or stand-alone diagnostic test.

RENALITIX AI

LEARN MORE
Client Services: (888) 203-2725 | clientservices@renalitixai.com | [KidneyIntelX.com](https://www.kidneyintelx.com)

Real-World Reactions



Low Risk

- “ OMG, this is the best news ever. I am so motivated to bring my number down lower than 40%. I plan to change my eating habits, when can I re-test to make sure that my number is heading in the right direction?
- “ I'm freaking happy. Thank you, Thank you. I work in a lab, so I know how important it is for me to diet and exercise to maintain or improve my numbers. I would love to be a spokesperson for your program. You people are amazing.
- “ My sister and mother died from diabetes and kidney problems. I am so happy! Please tell me what I can do to maintain?

Intermediate Risk

- “ I am willing to do anything to prevent dialysis, so please tell me what I can do to fix this? How often can I get this test?

High Risk

- “ This is not good news, but this information can be very helpful. When can I get the test done next. I want to see a nutritionist”
- “ This is disappointing. What do I have to do to prevent dialysis? Can the doctor up my medications. When can I be tested again?

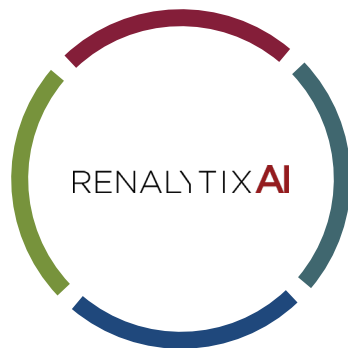
KidneyIntelX Could Drive ROI in 12–24 Months

Slowed Progression through CKD Stages

Better risk assessment & patient awareness
allows intervention to modify DKD progression

Positive Returns and Cost Savings for Health Insurers

KidneyIntelX could deliver cost
savings of up to \$1.3 billion over five
years per 100,000 patients with DKD¹



Delayed or Prevented Dialysis & Transplants

Early intervention can delay or prevent
dialysis and kidney transplant events

Fewer ER Events & Dialysis Crashes

Advanced warning of acute events
allows for planned dialysis

¹ Based on the Medicare price of \$950 per reportable test

Potential Near Term Major Value Drivers

- FDA Clearance and National Commercial Roll-Out
- National Medicare Coverage Determination Under MCIT
- Expanded indicated uses into broader disease categories, growing TAM
- Growing body of real-world health economics and utility data

An End-to-End Solution for Kidney Disease

RENALYTIX^{AI}
early risk assessment of kidney decline



Davita
comprehensive care management



**Help slow kidney disease progression,
improve care coordination and reduce costs**

- Anticipated launches in three major markets in 2021
- Expected outcome of the collaboration will also be used to expand indicated use claims for KidneyIntelX

Accretive Innovation to Renalytix Shareholders



- May '20 spin-out from Renalytix; shares distributed to Renalytix shareholders
- Kidney transplant Dx portfolio
- Oct '20 London Stock Exchange IPO (VRCI)
- Jan 11th market capitalization ~\$120M

- Renalytix / Mount Sinai Joint Venture
- Quantitative COVID antibody testing
- Partnerships
 - Biotechnie (NASDAQ TECH)
 - EKF Diagnostics (LSE EKF)
- Nov '20 CE Mark
- Dec '20 FDA EUA

Leadership Team



James McCullough
Co-Founder, CEO



Tom McLain
President & CCO



Fergus Fleming
Chief Technology Officer



O. James Sterling
Chief Financial Officer



Dr. Barbara Murphy, M.D.
Non-Executive Director



Dr. Steven Coca, DO
Co-Founder



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