

Renalytix

Company Overview

January 2022



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Leadership Team



James McCullough
Co-Founder, CEO

Prior experience
Exosome Diagnostics
Co-Founder, CEO
Liquid biopsy spin-out Harvard/MGH (2008)
Raised >\$50m Equity Capital (2008 – 2014)
\$575m Bio-Techne acquisition (2018)



Renwick Capital
Managing Partner (Since 2014)



Tom McLain
President

Prior experience
Exosome Diagnostics
General Manager, CEO
Built commercial, operational capabilities to drive national product launch (2015-2016)
Accelerated Medicare/ private payer coverage
\$575m Bio-Techne acquisition (2018)



Vermillion
President & CEO
Recapitalized company (2013); Positioned novel ovarian cancer diagnostic for clinicians, regulators, payers and patients (2013-2014)



Fergus Fleming
Chief Technology Officer

Prior experience
EKF Diagnostics
Senior Project Manger (2013-2018)
FF Consulting Limited
Managing Director
Provided Product Development and Commercialization support to Medical Devices and Diagnostics companies since June 2013



O. James Sterling
Chief Financial Officer

Prior experience
Renwick Capital
Managing Partner (Since 2015)
Brock Capital Group
Managing Director
Booz Allen (now Strategy&)
Management Consultant



Michael Donovan,
PhD, MD
Chief Medical Officer &
Laboratory Medical Director

Prior experience
Mount Sinai
Professor of Experimental Pathology and Director of the Biorepository and Pathology
Vigilant Biosciences
Chief Clinical Officer
Exosome Diagnostics
Chief Medical Officer



Steven Coca, DO
Co-Founder

Prior experience
Mount Sinai
Associate Professor of Medicine - Nephrology



Investment Highlights

3 Years Since Operations Began

KidneyIntelX™ is first validated advanced prognostic in early-stage kidney disease

Integrated directly into healthcare system EHRs

- ✓ Medicare National Price Award at \$950
- ✓ GSA Coverage Award at \$950
- ✓ AMA Distinct CPT Code
- ✓ FDA Breakthrough Device
- ✓ New York State Department of Health
- ✓ Multiple Private Payors including first regional Blue Cross Blue Shield plans

2022 Revenue Growth from

- ✓ Health System Partner Test Sales
- ✓ Strategic Activities

Growth Ecosystem

Health Systems



Strategics



Payor Lead Model



Education



Anticipated Calendar 2022 Milestones

>10M insured lives in 2022

- US Federal Government (GSA)
- Medicare
- Medicaid
- Expanding Private Payors

FDA de Novo Marketing Authorization


Multiple Hospital System Partnerships

Real World Evidence data read-outs


VA Health System Sales Force Expansion

Expanded Testing Agreements

Recent Events 3 Months

 Health system partnership with Singing River Health System




 Health system partnership with St. Josephs Health System



 KidneyIntelX testing initiated with Wake Forest Baptist Health System



 American Diabetes Association national care model/education program



 Positive study results on KidneyIntelX therapeutic monitoring published



 Direct sales force deployment in VA Medical system



Unprecedented Medical Need and Market Opportunity

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

\$1.1 billion¹

can be saved over 5 years per 100,000 early-stage DKD patients receiving KidneyIntelX informed care

2022 KidneyIntelX™ is expected to have insurance payment for

>10M lives₂

Source: McCullough, KP, et al. J Am Soc Nephrol. 2019;30:127–135
¹<https://www.tandfonline.com/doi/full/10.1080/13696998.2021.1960714>
²Assumes Medicare payment established in calendar 2022

Urgent and Immediate Need to Clarify Who Has Progressive Kidney Disease

1 in 5

will rapidly progress
to kidney failure




**Who
Is It?**



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


Powerful and Clear Prediction for Improved Kidney Health



Standard blood draw
3 proprietary biomarkers



Validated algorithm



Past and present features from patient EHR




KidneyIntelX™

Test Report

Ordered by		Dr. XXXXXXX	
Collection Date		8/14/2020	
Report Date		8/19/2020	
Specimen ID		XXXXXX	

PATIENT INFORMATION			
NAME	SEX	DATE OF BIRTH	MEDICAL RECORD #
Patient Name	X	00-00-0000	00000000

RISK OF PROGRESSIVE DECLINE IN KIDNEY FUNCTION



95


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

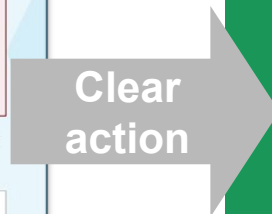
The KidneyIntelX score ranges from 0-100 and correlates with the probability of progressive decline in kidney function in the study population. Risk classification is provided to guide interpretation of the risk score using cut-offs related to clinical outcomes.

SIGNED	DATE	TIME
Laboratory Director: Michael J. Donovan PhD, MD, CLIA, Renalytix AL 101 6th Ave, 3rd Floor, Room 324 New York, NY 10013 CLIA Number: 3302256875		
This test was developed and its performance characteristics determined by Renalytix AL 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 ¹		Comprehensive Strategy to Maximize Protection for Diabetic Kidney Disease Progression and Cardiovascular Disease ^{2,3}	
Monitoring 3x/year	Nephrology Referral	Titrate ACEI or ARB to maximally tolerated dose	Strongly consider SGLT2 inhibitor therapy unless contraindicated

¹ KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_CG1.pdf
² Executive Summary of the 2020 KDIGO Diabetes Management in CKD Guideline <https://doi.org/10.1016/j.kint.2020.06.024>
³ ADA guidelines https://care.diabetesjournals.org/consensus/43/Supplement_1/333B

 renalytix



Precise therapeutic management



Improved kidney health

Integrated Health System Model Drives Utility and Care Quality

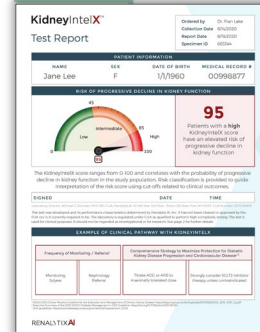
Hospital Care Coordinator

- Identifies Eligible Patients in System for risk assessment
- Pre-pends KidneyIntelX™



Primary Care Visit

- KidneyIntelX score automatically transmitted to PCP in the EHR
- Care Navigation follows



Care Team Follow-up

Dietician / Pharmacist / Clinical Coordinator

Care Management

- Patient office and telephone follow up
- Detailed chart reviews
- Pharmacy management
- Education on kidney disease
- Activate Specialist Referral

Process Outcomes

- Optimized pharmacy management including SGLT2i / RAASi / finerenone
- Appropriate referrals
- Lifestyle / dietary changes

Driving & Tracking Outcomes

- Maintain Kidney Health
- Reduce Kidney Decline
- Reduce Crash Dialysis Starts
- Reduce Hospitalizations
- Optimize Care Resources

Integrated Model Enables Significant Value for Renalytix



Electronic market access to large body of treating physicians



Population health engagement to educate/support PCP base



Long-term competitive barriers to market entry



Cost savings enables value based care arrangements with payers



Continuous data for broad payment, RWE, product improvements



Focus on compliance and quality control enables scale



True Value Based Care



Better patient care



Lower cost

Growth Opportunities in Multiple Market Segments

	Current	Current	Calendar 2022	Calendar 2023
	Mount Sinai	US Government	Anticipated U.S. Expansion	TAM Multipliers
Growth Drivers	<ul style="list-style-type: none"> Anticipated expansion up to 10,000 RWE tests at \$950/test 	<ul style="list-style-type: none"> VA Health System Deployment 	<ul style="list-style-type: none"> 20 Health System Partnerships Total 	<ul style="list-style-type: none"> Repeat test monitoring Expanded indicated uses
TAM	<ul style="list-style-type: none"> ~71,000 DKD patients ~251,000 CKD patients 	<ul style="list-style-type: none"> ~400,000 DKD patients >1M CKD patients 	<ul style="list-style-type: none"> TAM >1M DKD patients 	<ul style="list-style-type: none"> ~40M CKD patients

Note: Addressable market figures are estimates based on publicly available information and generally recognized population disease percentages, and may include current and future expected KidneyIntelIX™ product versions and indicated uses

Health Economics – A Major Driver to Adoption

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 \$1.1 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 <https://www.tandfonline.com/doi/full/10.1080/13696998.2021.1960714>

Calendar 2022 Milestone Events



**20 health system
partnerships target**



**Expanded payment
w/Medicare & private
insurance**



**FDA de Novo
Marketing
Authorization**



**Strategic
partnerships**