

ARTIFICIAL INTELLIGENCE FOR KIDNEY DISEASE

RENALYTIX **AI**



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Presenter recent experience



James McCullough
Chief Executive Officer

RenalytixAI

Co-Founder, CEO

Artificial Intelligence Kidney Diagnostics

Exclusive partnership Icahn School of Medicine at Mount Sinai
2018

RENALYTIX**AI**

Exosome Diagnostics

Co-Founder, CEO

Liquid biopsy spin-out Harvard/MGH 2008

Raised >\$50m Equity Capital 2008 – 2014

\$575m Bio-Techne acquisition 2018



PAIGE.AI

Co-Founder

Artificial Intelligence Computational Pathology spin-out Sloan

Kettering 2018

Completed \$25m equity financing 2018

PAIGE



Julian Baines
Chairman

EKF Diagnostics

CEO

Global medical device manufacturer

Completed 8 acquisitions in 7 countries

Built revenue from £0 to £40m+

Overseen fundraisings 2010, 2011, 2014



BBI Holdings

Group CEO

Management buyout 2000

Flotation on AIM 2004

£85m acquisition by Alere Inc. 2008

Presenter recent experience (continued)



Barbara Murphy, MD
Proposed Non-Exec Director

Mount Sinai Health System
***Murray M. Rosenberg Professor of Medicine and
Chair of the Samuel Bronfman Department of
Medicine***

Specialist in transplant immunology

Icahn School of Medicine
Dean of Clinical Integration and Population Health

Other positions and awards

Councillor, American Society of Nephrology
American Kidney Fund Nephrologist of the Year (2011)
Jacobi Medallion recipient (2014)
President of the American Society of Transplantation (2008)



Erik Lium, PhD
Proposed Non-Exec Director

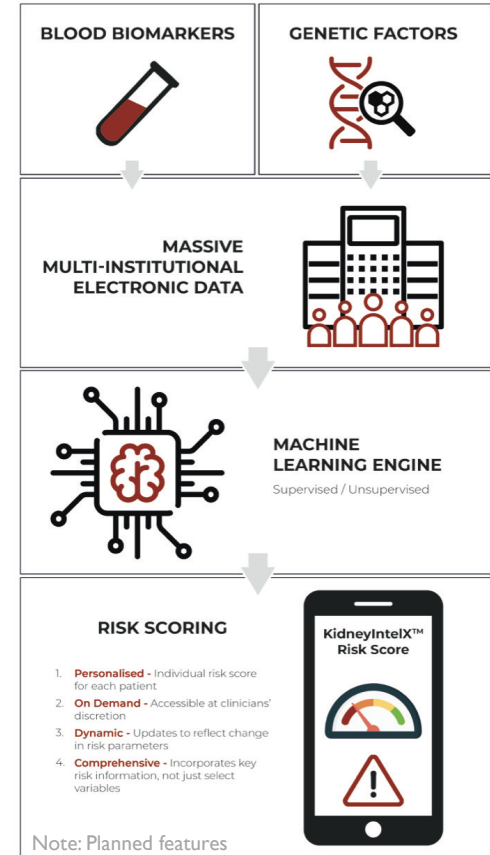
Mount Sinai Innovation Partners
Executive Vice President
Oversees technology commercialization
Mount Sinai Health System

UC San Francisco
Assistant Vice Chancellor
Served in several roles managing innovation, technology and
licensing



Overview of RenalytixAI

- Developing artificial intelligence (“AI”) enabled clinical decision support tools for improved kidney disease risk assessment and clinical care
- Addressing one of the largest and costliest chronic medical conditions globally, estimated to affect over 850 million people worldwide, with a significant portion unaware that they are at high-risk
- Established in 2018 as a collaboration with the Icahn School of Medicine at Mount Sinai, the medical school for the Mount Sinai Health System, a world-renowned healthcare provider based in New York
- Expecting to launch *KidneyIntelX™*, a product solution that uses AI to analyse kidney patient data and predict outcomes, in 2019



“The state of affairs in kidney disease is so poor that a quantum leap is available to us with artificial intelligence.

We can transform how we identify, monitor and treat one of the largest and costliest diseases in history.”

Dr. Steven Coca, Co-Founder, RenalytixAI
Associate Professor, Medicine, Nephrology
Associate Chair for Clinical and Translational Research for the Department of Internal Medicine
Icahn School of Medicine at Mount Sinai

Our approach

- Building one of the deepest pools of EHR-linked kidney disease data for AI application development
- Decision support solutions for at-risk diabetic and African ancestry populations served by major medical centers
- Cornerstone collaboration with the Icahn School of Medicine at Mount Sinai in May 2018
- *KidneyIntelX™* expected to be first AI-enabled kidney disease solution for FDA submission
- Expected to begin \$6.0M in revenue during 2019 under clinical utility period
- Securing major vendors to support product development and launch, and international growth
- Building on a proprietary intellectual property portfolio

**AI-driven clinical support solutions for
improved identification and management of kidney disease**

Investment case

Very large addressable market

Kidney disease is one of largest
unmet medical needs today

Expected first

Expected to be first to submit
AI-enabled kidney disease products
to FDA

Cornerstone deal in place

Mount Sinai collaboration provides
access to 3M patient records and
large at-risk population groups

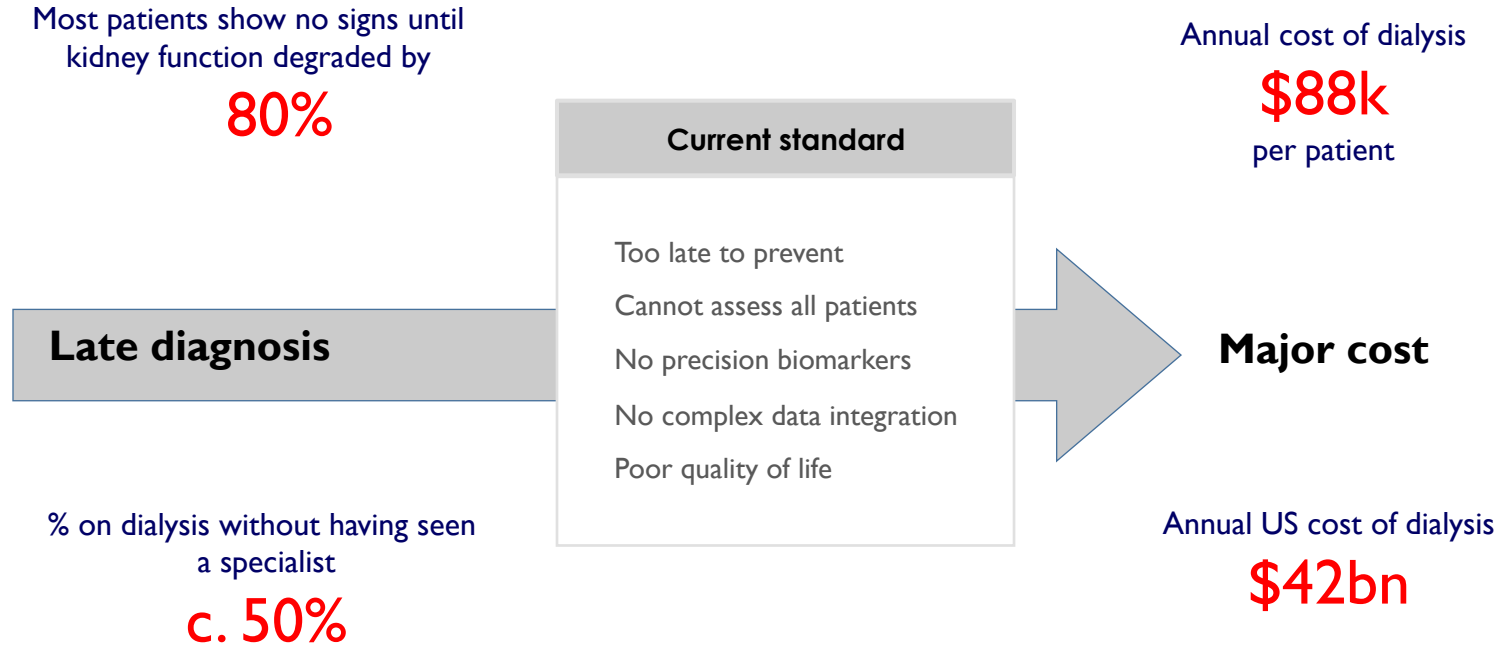
Efficient deployment of capital

Cloud based data access/ reporting
& robust outsourcing to minimize
fixed overhead

Disruptive shift in reimbursement law

Protecting Access to Medicare Act
(PAMA) supports shift in pricing
power to private market

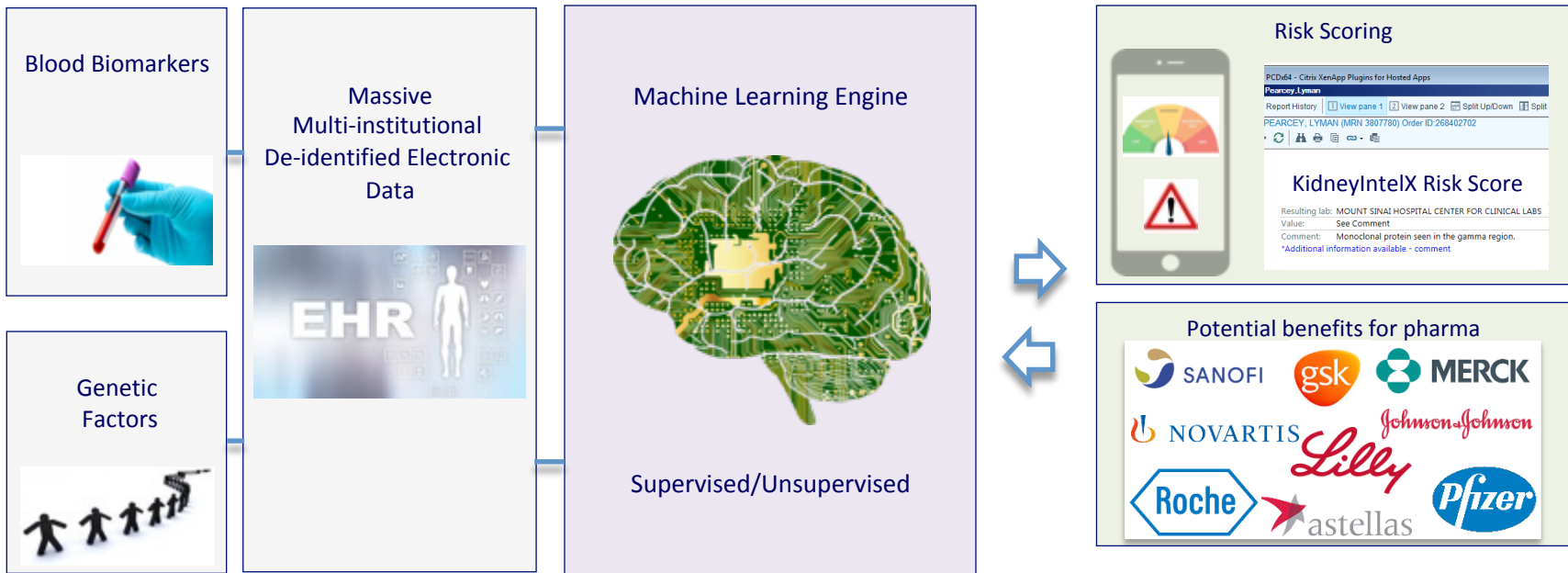
A public epidemic: current standard not working



Source: WHO; United States Renal Data System, National Kidney Foundation, NHS Kidney Care

KidneyIntelX™ - Launch product

- Expected to be first AI-driven solution in kidney disease submitted for FDA review
- Low barriers to adoption with custom report capability to primary care, diabetology, endocrinology, nephrology



Revenue strategy

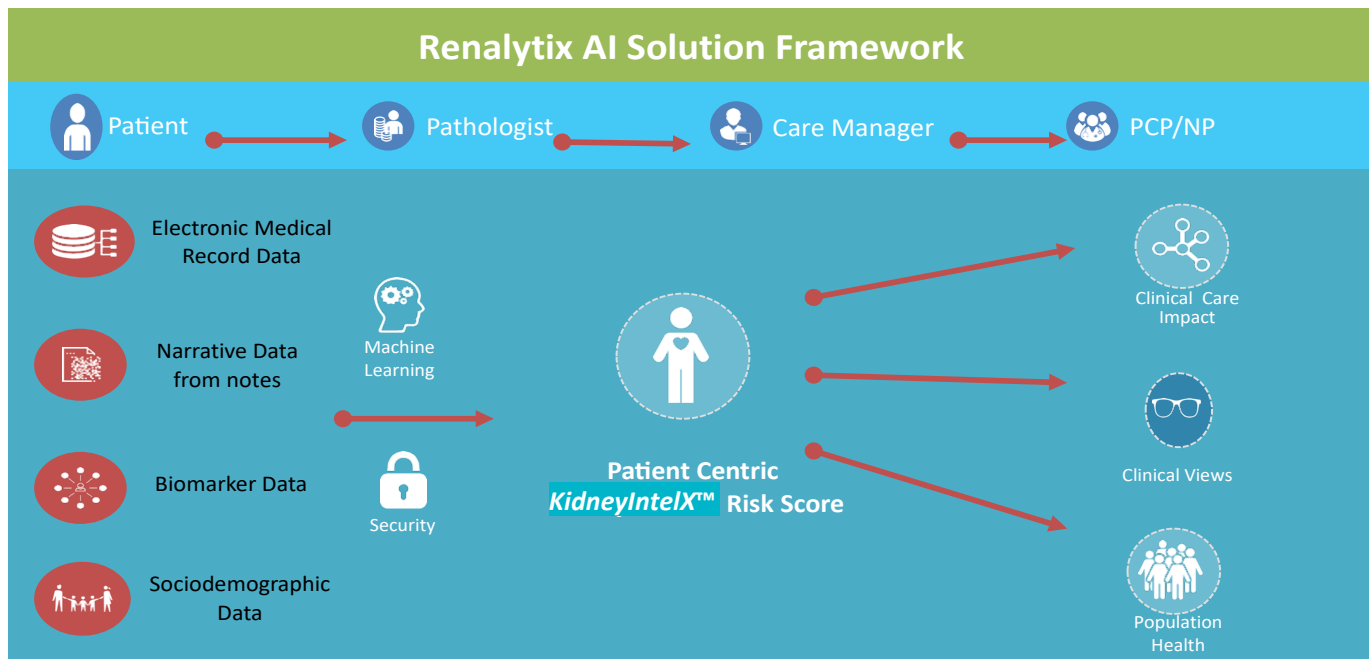
The Company's revenue is expected to be derived from different sources including:

- (1) Third-party and government reimbursement models for developed products, such as *KidneyIntelX™*
- (2) Subscription models (e.g. quarterly) for ongoing monitoring of kidney risk
- (3) Program development and ongoing contract fees for proprietary products, to support pharmaceutical companies with clinical trials and drug target discovery

Highly scalable platform learning from diverse data sources

Designing platform with capability to integrate with major electronic health record (EHR) systems

Building for mobile, web and hospital EHR result reporting



Major data access and product development partnership

License and collaboration agreement May 2018:

- ISMMS expected to purchase up to \$6.0M *KidneyIntelX™* tests beginning 2019*
- Large diabetes and African ancestry populations
- 3,000,000 electronic health records
- 43,000 patient unique biobank

Mount Sinai is expansive health system:

- More than 5,500 associated physicians
- 8 hospitals
- 300 locations
- 3.1 million out-patient visits



Forbes

3,059 views | Jun 8, 2018, 02:47pm

See How This Hospital Uses Artificial Intelligence To Find Kidney Disease



The role of artificial intelligence (AI) in healthcare continues to rise.

Mount Sinai and RenalytixAI will put more than 3 million patient health records into the AI tool to identify at-risk patients. By automating the process of analyzing large volumes of data, the team hopes to reduce diagnostic errors, expedite detection and free hospital staff to focus on care. Both parties indicate they hope to commercialize the new AI product Q2 2019.

"By partnering with a major healthcare system like Mount Sinai, we can really define the clinical impact of AI-driven products in kidney

* Subject to certain conditions including successful validation, IRB approval and completion of clinical testing agreements

Partnering with a software development leader to build technology platform



PERSISTENT

800+ customers:
14 top technology
companies



Publically listed in
India (BSE, NSE)



\$470m FY'18
revenue



28+ years
in business



5,500+ product
releases since 2012



Source: Persistent marketing presentation

KidneyIntelX™ - Convergence of 'Big Data' and key biomarkers

Implications for improved diagnosis, prescriptions, outcomes and cost with proprietary biomarkers

Dynamic updated risk scoring with AI EHR interface

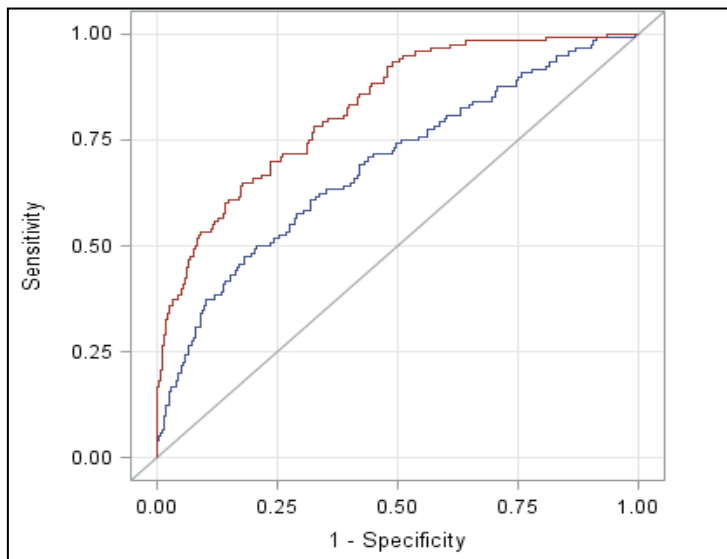
KidneyIntelX™ AUC 0.82

vs.

Standard of Care AUC

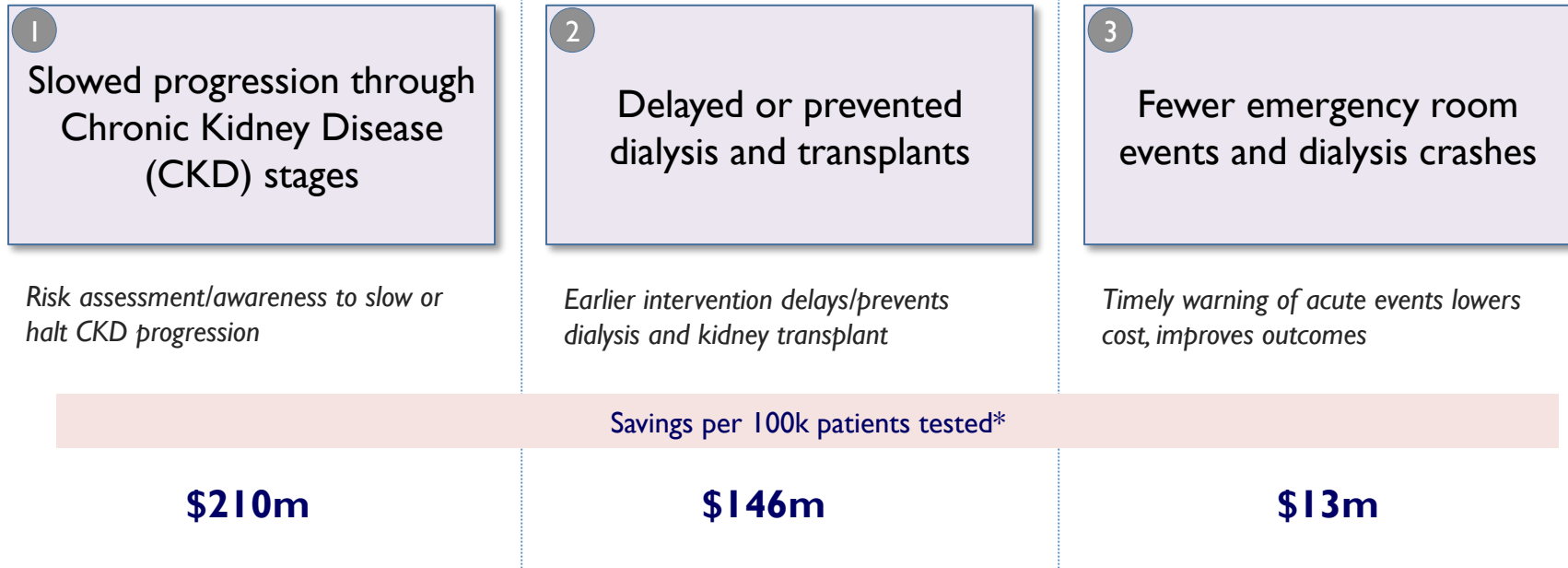
0.68*

(n = 871)



* Results generated by ISSM investigators Steven Coca, MD and Girish Nadkarni MD using the Mount Sinai BioMe Cohort.

KidneyIntelX™ - Analysis of expected cost savings



* Potential gross savings over first five years. After accounting for testing and preventative measures costs, aggregate net savings of \$250m per 100,000 patients expected

Source: Golestaneh et al., "Longitudinal Study of Chronic Kidney Disease Progression and Associated Costs," Nov, 2017; Coresh et al., "Decline in Estimated Glomerular filtration rate and subsequent risk of end-stage renal disease and mortality," June, 2014; Maneesh et al., "Progression to Stage 4 chronic kidney disease and death, acute kidney injury and hospitalization risk: a retrospective cohort study," Nov, 2015; United States Renal Data System 2017 Annual Data Report; Company analysis

Demonstrated short & long term behavior, cost, mortality impact

Utility	Description	Peer review
Therapeutics	Drug interventions (ACEi/ARB, aggressive BP control) to reduce risk for decline in kidney function and CVD in patients at risk/with CKD	ACEi/ARB (multiple) Aggressive BP Control (AASK, SPRINT)
Therapeutics	SGLT2i Ameliorate decline in kidney function and reduce CVD and HF and all-cause mortality	EMPA-REG Trial (NEJM 2015) CANVAS Trial (NEJM 2017) CKD Subgroup CANVAS (Circulation 2018) CANVAS Renal Outcomes (Lancet 2018)
Behavior	Demonstrated healthier lifestyles with patients flagged at high genetic risk	GeneRISK Study 2018
Behavior	Reporting of APOL1 genotype resulted in 23% increase in number with SBP Controlled to < 140 mm Hg	GUARDD Trial 2018
Work-Flow	Earlier referral to nephrologist reduces mortality by 35%, reduced number and length of hospitalizations, 70% more likely to choose PD over HD	Cochrane Research Group 2014
Multi-disciplinary Care for CKD	Reduced mortality by 38% reduced progression to ESRD by 41% increased quality-adjusted life-years Cost-effective even when costs artificially inflated 5-fold	Eur J Intern Med 2015 PLOS Medicine 2018

Product and service evolution from deep proprietary data pool

	Indication	Stage	Price*	
KidneyIntelX APOL1	African Ancestry	Clinical Validation	\$ 600	Major Value Driver
KidneyIntelX Type II	Type II Diabetes	Clinical Validation	\$ 600	
FractalDx	Kidney Transplant	Clinical Validation	\$2500	
Kidney Disease Subtype				Deep Data Pool Powered by ongoing patient testing and multi-institution data access
Acute Kidney Injury		Continuous performance improvement		
Drug-induced Kidney Injury				
Pharma Development				
Clinical trial patient enrollment	Kidney Disease		Project	
Drug response tracking	Kidney Disease		Project	
New druggable targets	Kidney Disease		Project	

* Targeted price. For FractalDx, subject to exercise of related option

Expected milestones to launch and growth

2018

- ▶ Collaboration with ISMMS
- ▶ KidneyIntelX™ CLIA validation
- ▶ KidneyIntelX™ FDA pre-sub

Collaborators



2019

- ▶ KidneyIntelX™ multi-center utility begins
- ▶ KidneyIntelX™ FDA full submission
- ▶ FractalDx CLIA validation
- ▶ FractalDx FDA pre-sub
- ▶ **Begin revenue**

2020-2021

- ▶ FDA clearances
- ▶ CMS reimbursement
- ▶ Multi-center adoption
- ▶ KidneyIntelX™ IVD kit process

In dialogue with

Montefiore



Indicative Use of Proceeds (£m)







£21m Net Raise	
Product Development / AI	4.7
Corporate	4.2
Licenses & Royalties	9.3
Capex	0.4
Working Capital	1.5
Reserve	<u>21.0</u>

£25m Net Raise	
Product Development / AI	7.1
Corporate	4.4
Licenses & Royalties	9.3
Capex	0.7
Working Capital	1.7
Reserve	<u>25.0</u>

Notes

1. Initial license and patent costs of FractalDx opportunity (c. £1 million) included in both scenarios
2. Figures shown net of expected benefits from grant income (c. £1.5m) and GM contribution (c. £6m to March 2021)
3. Product Development / AI: includes machine learning / software engineering, scientific development and clinical partnerships
4. Corporate: includes professional services (legal, reimbursement, etc.), overhead, business development and office expenses
5. Additional funding in £25m scenario allows expanded clinical validation and technology development

“Exit” comparables

Company name	Investing entity	Company description	Implied Valuation	Deal type	Date
 flatiron		Accelerating cancer research through oncology data analytics	\$2.3bn	Acquisition	April 2018
 iCarbonX 碳云智能		An ecosystem of digital life based on the combination of consumers' big life data, internet and artificial intelligence.	\$1bn	Funding	2016
 BenevolentAI		AI to combat the mismatch between healthcare information. Early success through discovering a new compound, which has since been shown to delay the progression of motor neuron disease	\$1.8bn	Funding	2015

IPO Summary

Fundraising comprises Placing, Subscription (US Reg D Placement) and Restricted Offer (to EKF shareholders only)

Total size: £21 – 25m

Value: £43 – 55m pre-new money

Fundraising shares: 30.4% – 32.8% of enlarged share capital

EKF residual holding: c.39.8% – 41.2% (pre Distribution to EKF shareholders via dividend *in specie*)

Expected Timetable **2018**

Roadshow: 12 – 25/26 September

Bookbuild: from 21 September (book close 26 September)

Pricing/ allocation: 27 September

Pricing announcement: 28 September (Placing and Subscription)

Restricted Offer open: 1 – 12 October inclusive (result announced 15 October)

Admission: By 16 October

Contact: Tom Salvesen (Corp. Broking)

tom.salvesen@nlsinger.com

T: +44 20 7496 3054

ALL DATES ARE SUBJECT TO AMENDMENT BY N+I SINGER AND THE COMPANY

Glossary

“ACEi”	Angiotensin converting enzyme inhibitor	“ESRD”	End stage renal disease
“APOLI”	Apolipoprotein L-I	“FDA”	US Food and Drug Administration
“ARB”	Angiotensin receptor blockers	“GM”	Gross margin
“AUC”	Area under the plasma drug concentration-time curve	“HD”	Home hemodialysis
“BP”	Blood pressure	“HF”	Heart failure
“BCBS”	Blue Cross Blue Shield	“PAMA”	Protecting Access to Medicare Act of 2014
“CKD”	Chronic kidney disease	“PD”	Peritoneal dialysis
“CLIA”	Clinical Laboratory Improvements Amendments 1988	“SBP”	Spontaneous bacterial peritonitis
“CMS”	Centers for Medicare & Medicaid Services	“SGLT2i”	Sodium-glucose co-transporter-2
“CVD”	Cardiovascular disease	“sTNFR”	Soluble tumor necrosis factor receptors
“EHR”	Electronic health record		

SUPPLEMENTAL

Board and Management



James McCullough, CEO, Executive Director

Partner, Renwick Capital; former CEO, Exosome Diagnostics; founding advisor, PAIGE.AI



Julian Baines, Executive Chairman

Group CEO, EKF Diagnostics Holdings plc; former CEO & Managing Director BBI Holdings plc



Christopher Mills, Non-Executive Director

CEO and Partner, Harwood Capital LLP; CEO and Investment Manager North Atlantic Smaller Companies Investment Trust



Erik Lium, PhD, Non-Executive Director

EVP Mount Sinai Innovation Partners, Assistant Vice Chancellor of Innovation, Technology & Alliances at UCSF



Barbara Murphy, MD

Murray M. Rosenberg Professor of Medicine; Chair of the Department of Medicine for the Mount Sinai Health System; Dean for Clinical Integration and Population Health



Richard Evans, MBA, Non-Executive Director

CFO EKF Diagnostics Holdings plc; Finance Manager, Global Account Director at Hitachi Data Systems



O. James Sterling, CFO

Partner, Renwick Capital; former managing director, Aleutian Capital and Brock Capital Group; management consultant, Booz Allen



Fergus Fleming, CTO

Managing Director, FF Consulting; former senior project manager, EKF Diagnostics Holdings plc

Advisory Board



Barbara Murphy, MD, Chair of Advisory Board
Murray M. Rosenberg Professor of Medicine;
Chair of the Department of Medicine for the Mount
Sinai Health System; Dean for Clinical Integration and
Population Health



Steve Coca, MD, co-Founder
Associate Professor, Medicine, Nephrology;
Associate Chair for Clinical and Translational
Research for the Department of Internal Medicine,
Mount Sinai Health System



John Cijiang He, MD
Professor of Medicine and Pharmacological
Sciences, Irene; Dr. Arthur Fishberg endowed Chair
of Nephrology, Mount Sinai Health System



Chirag R Parikh, MD, PhD, FACP
Professor of Medicine and the Director of the
Program of Applied Translational Research in the
Department of Medicine, Yale University School
of Medicine



Girish Nadkarni, MD, co-Founder
Assistant Professor of Medicine, Division of
Nephrology; Clinical Director of the Charles
Bronfman Institute for Personalized Medicine Mt.
Sinai Health System



Judy Cho, MD
Director and Associate Dean for Precision
Medicine, Ward-Coleman Professor of Translational
Genetics and Medicine Mount Sinai Health System



John Quackenbush, PhD
Professor of Computational Biology and
Bioinformatics, Harvard T.H. Chan School of Public
Health; Professor of Cancer Biology, Dana-Farber
Cancer Institute



Joseph Boystak
Managing Partner, Health2047 Inc; CEO,
Brightwaters Partners LLC; Former founding
managing director, Jefferies & Company, Inc

Intellectual property

- Multi-year license and collaboration with ISMMS to develop AI-enabled and other applications in kidney disease
- Strategy built around AI integration of ISMMS proprietary data, including EHR and BioMe™ biobank patient records, and analysis of kidney disease biomarkers
- Key biomarkers for kidney disease, including sTNFR I/2 licensed from Joslin Diabetes Center (to be transferred from EKF to RenalytixAI)
- Represented by Cooley

The logo for Cooley, featuring the word "Cooley" in a bold, red, sans-serif font.

Robust validation and utility study to support FDA and CMS process



2018 pre-submission

2018 kick-off meeting



October 2018 in-person process begins

2018 Validation Study Objectives

- ▶ 4,000 patients (retrospective)
- ▶ Expected participation



**Mount
Sinai**



Perelman
School of Medicine
UNIVERSITY of PENNSYLVANIA



EMORY
UNIVERSITY

- ▶ Algorithm validation
- ▶ Confirm predictive power
- ▶ High-impact publications for future FDA and reimbursement process

2019/20 Utility Study Objectives

- ▶ 5,000 patients (prospective)
- ▶ 15,000 test points
- ▶ Demonstrate short and long term utility/impact
- ▶ Health economics impact
- ▶ High-impact publications to support filing for expanded reimbursement
- ▶ Continue prospective end-points

Strategy to mitigate risk, time to reimbursement

Large concurrent utility data and commercial strategy helps drive adoption

- ▶ Robust utility studies
- ▶ High-rank peer review publications
- ▶ Planned FDA clearance
- ▶ Pricing at \$600 per test (*KidneyIntelX™*)*
- ▶ Demonstrating benefit to price ratio > 3x
- ▶ Patient advocacy involvement
- ▶ Guidelines inclusion
- ▶ Early adopter private pay (e.g. BSBC MD)
- ▶ Leading investigator advocates

Utility and impact

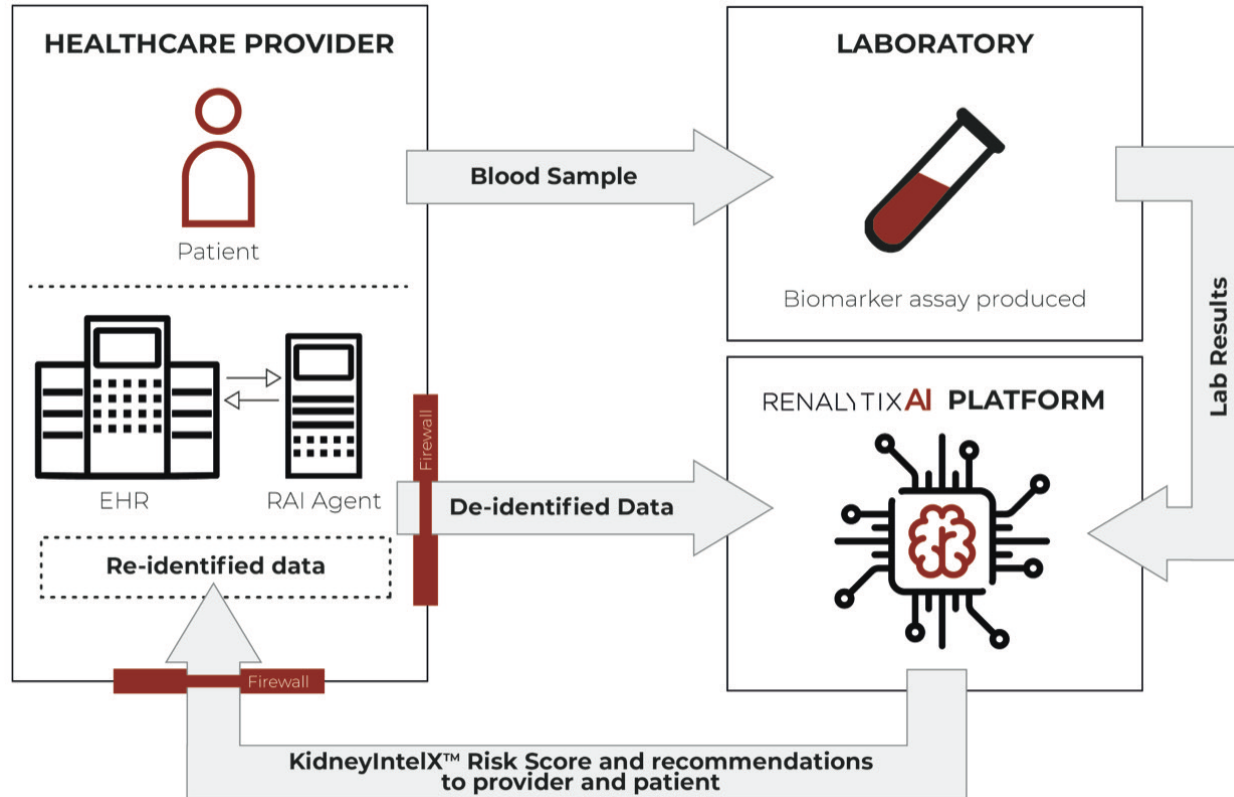
Commercial adoption

- ▶ Utility study revenue establishes invoice price (PAMA)
- ▶ Real-world clinical work-flow experience and refinement to be demonstrated

15K+
test points

* Targeted price

KidneyIntelX™ process



Contact

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