



Renalytix Launching KidneyIntelX in Veterans Health Administration Hospitals

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Jed Fulk Appointed Vice President Sales, Government Accounts

NEW YORK and SALT LAKE CITY, Oct. 07, 2021 (GLOBE NEWSWIRE) -- [Renalytix plc](#) (NASDAQ: RNLX) (LSE: RENX) today announced the expansion of its commercial strategy to address early-stage kidney disease in the Veterans Health Administration patient population with the appointment of Jed Fulk to the position of Vice President Sales, Government Accounts. Mr. Fulk is developing and leading a team expected to grow to 42 regional sales managers and account executives during calendar year 2022 to support [KidneyIntelX™](#) rollout to the VA Health System. KidneyIntelX will be deployed to help VA primary care physicians to identify diabetic kidney disease (DKD) patients at high and low risk for rapid progression and kidney failure.

The Veterans Health Administration is America's largest integrated health care system, providing care at 1,293 health care facilities, including 171 medical centers and 1,112 outpatient sites of care of varying complexity (VHA outpatient clinics), serving nine million enrolled Veterans each year. The Veteran population has an approximately one-third higher chronic kidney disease (CKD) and DKD prevalence than the general population, which has been attributed to the significant multi-morbidity and higher mean age in this group. The prevalence of DKD in Veterans is estimated to be between 4% (most conservative DKD definition) and 14% (liberal definition of DKD); meaning 0.5 to 1.0 million individuals.¹

The economic costs for providing healthcare for Veterans with kidney disease are high and are increasing at a rapid rate. Excluding costs associated with dialysis, \$17.9 billion was spent on care for Veterans with CKD in 2014. An update to the VA/DoD Clinical Practice Guideline for the Management of CKD released in 2020 identified the need for accurate risk assessment in patients with early-stage kidney disease. KidneyIntelX and associated care management tools provide information that is essential to realizing the directive's goals for appropriate pharmacy management, promoting communication and collaboration between care providers, particularly between nephrologists and primary care physicians and developing a patient-centered plan for treatment and education about kidney disease.

Renalytix was awarded a 10-year Governmentwide Acquisition Contract (GWAC) in April 2021 to provide KidneyIntelX early-stage kidney disease testing services. The contract, offered through the General Services Administration (GSA), covers KidneyIntelX laboratory testing services that can be provided through more than 140 U.S. government departments, agencies and affiliates, including the U.S. VA. The GSA contract enables Renalytix to initiate efforts towards multiple integrated model deployments with government hospital systems.

Mr. Fulk is a graduate of West Point and brings over 25 years of extensive senior leadership experience including strategic, operational, and tactical military assignments in the U.S. and Europe. Mr. Fulk was Company Commander in the 10th Mountain Division and a Company Commander in the NYC Army Recruiting Battalion. Most recently he served as VP of Sales and Marketing at OPKO Health managing 4KScore, a test for assessing the risk of aggressive prostate cancer. Preceding OPKO he served as Executive Vice President of Sales and Marketing at Bostwick Laboratories managing over 200 employees. Mr. Fulk is currently focused on recruiting a team of Veterans and sales executives with VA experience to introduce KidneyIntelX informed care in the context of the CKD care directive. Mr. Fulk is not being appointed to the board of Renalytix.

About KidneyIntelX

KidneyIntelX, is a first-of-its-kind solution that enables early-stage DKD progression risk assessment by combining diverse data inputs, including validated blood-based biomarkers, inherited genetics, and personalized patient data from electronic health record, or EHR, systems, and employs a proprietary algorithm to generate a unique patient risk score. This patient risk score enables prediction of progressive kidney function decline in CKD, allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk.

About Renalytix

Renalytix (NASDAQ: RNLX) (LSE: RENX) is the global founder and leader in the new field of bioprognosis™ for kidney health. The company has engineered a new solution that successfully enables early-stage chronic kidney disease progression risk assessment. The Company's lead product, KidneyIntelX, has been granted Breakthrough Designation by the U.S. Food and Drug Administration and is designed to help make significant improvements in kidney disease prognosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery (visit www.kidneyintelx.com). For more information, visit www.renalytix.com.

About the General Services Administration Contracting Program

The General Services Administration (GSA) is an independent agency of the United States government established in 1949 to help manage and support the basic functioning of federal agencies. Their responsibilities include the Federal Acquisition Service. The GSA Schedule (also referred to as Multiple Award Schedule (MAS) and Federal Supply Schedule) is a long-term governmentwide contract with commercial firms providing federal, state, and local government buyers access to more than 11 million commercial products and services. GSA contracts fix the rate paid for government work making it much easier to structure individual agency and department contracts. Listing on the Federal Supply Schedule also allows purchases up to defined minimum thresholds without a contract. Laboratory and medical services covered under GSA contracts are generally provided to military veterans, active military, and Native American Tribes. Laboratory services access can also be provided to certain employees of the Federal government including members of the US Senate and US House of Representatives.

Sources

1: Saran R, Pearson A, Tilea A, et al. Burden and Cost of Caring for US Veterans With CKD: Initial Findings from the VA Renal Information System (VA-REINS). *Am J Kidney Dis.* 2021;77(3):397-405.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Examples of these forward-looking statements include statements concerning: the commercial prospects of KidneyIntelX, including whether KidneyIntelX will be successfully adopted by physicians and distributed and marketed, the rate of testing with KidneyIntelX in health care systems, expectations and timing of announcement of real-world testing evidence, the potential for KidneyIntelX to be approved for additional indications, our expectations regarding reimbursement decisions and the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery and improve patient outcomes. Words such as “anticipates,” “believes,” “estimates,” “expects,” “intends,” “plans,” “seeks,” and similar expressions are intended to identify forward-looking statements. We may not actually achieve the plans and objectives disclosed in the forward-looking statements, and you should not place undue reliance on our forward-looking statements. Any forward-looking statements are based on management’s current views and assumptions and involve risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. These risks and uncertainties include, among others: that KidneyIntelX is based on novel artificial intelligence technologies that are rapidly evolving and potential acceptance, utility and clinical practice remains uncertain; we have only recently commercially launched KidneyIntelX; and risks relating to the impact on our business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in our filings with the Securities and Exchange Commission (SEC), including the “Risk Factors” section of our annual report on Form 20-F filed with the SEC on October 28, 2020, and other filings we make with the SEC from time to time. All information in this press release is as of the date of the release, and we undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Media Contacts:

United States:

Jennifer Moritz

Zer0 to 5ive for Renalytix

(917) 748-4006

jmoritz@0to5.com

Outside of the United States:

Walbrook PR Limited

Paul McManus / Lianne Cawthorne

Tel: 020 7933 8780 or renalytix@walbrookpr.com

Mob: 07980 541 893 / 07584 391 303

UK Investor Contact:

Walbrook PR Limited

Paul McManus / Lianne Cawthorne

Tel: 020 7933 8780 or renalytix@walbrookpr.com

Mob: 07980 541 893 / 07584 391 303

US Investor Contact:

CapComm Partners

Peter DeNardo

investors@renalytix.com

415-389-6400