



Renalytix and Steno Diabetes Center Announce Precision Medicine Collaboration Marking First Expansion for KidneyIntelX Platform Beyond US

July 11, 2024

LONDON and NEW YORK, July 11, 2024 (GLOBE NEWSWIRE) -- Renalytix plc (NASDAQ: RNLX) (LSE: RENX), an artificial intelligence-enabled in vitro diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and advance value-based care, announces a collaboration with the Steno Diabetes Center ('Steno'), Copenhagen, to advance translation of precision medicine solutions for patients with Diabetes and Chronic Kidney Disease (DKD). The initial focus of the collaboration will be on developing a roadmap for implementation of KidneyIntelX at the Steno Diabetes Center and affiliated practices.

Through this collaboration Renalytix and Steno will investigate core elements necessary for successful clinical translation of KidneyIntelX in a European context, beginning with integration of the biomarker testing into laboratory workflows, education of clinicians and patients on the role of KidneyIntelX risk assessment in the continuum of care and, leveraging of electronic health record systems for efficient, risk-based care management. Importantly, this is expected to launch the first use of Renalytix's KidneyIntelX platform outside the US to showcase the clinical utility in the EU by utilizing advanced technology to provide better informed care for solving chronic kidney disease.

Professor Peter Rossing, Senior Principal Investigator at the Steno Diabetes Center said: *"The availability of multiple proven therapies in recent years to slow or prevent kidney function decline in patients with diabetes presents us with an opportunity to significantly reduce the suffering of patients. Access to biomarker-based, precision medicine tools such as KidneyIntelX in clinical practice will be critical in ensuring individual patients receive the right treatment as early as possible in the disease cycle."*

Steno Diabetes Center Copenhagen, which offers tailored diabetes treatment for people with diabetes, has been at the forefront of innovation in diabetes care since its inception and has been proclaimed by the World Economic Forum to be a world-leading role model from which other countries and healthcare systems can learn.

Dr. Frederik Persson, Head of Clinic at Steno Diabetes Center added: *"At Steno, we recognize the importance of bridging the translation gap for novel technologies to clinical practice so that our patients and providers have access they need for optimized care and outcomes. We look forward to working with Renalytix in introducing the FDA approved KidneyIntelX test to patients in our practices and beyond."*

Additional elements to be addressed include requirements for CE marking in the EU under the In-Vitro Diagnostic Regulation, clinical utility data, cost effectiveness analysis and, ultimately, clinical adoption in accordance with national and international clinical guidelines. The outputs of the collaboration will contribute to defining a framework for implementation of precision medicine solutions based on novel biomarkers in clinical practice, including helping to define requirements for future product development of tests by Renalytix to predict and monitor therapeutic response in DKD.

Fergus Fleming, CTO of Renalytix commented: *"We welcome the opportunity to work with such a prestigious team at Steno Diabetes Center as we seek to expand access to KidneyIntelX and the promise of precision medicine to patients in Europe and other territories internationally. The insights gained from this collaboration will be pivotal in informing our commercialization and product development activities in the US and abroad."*

Renalytix and Steno are partners in PRIME-CKD (<https://www.prime-ckd.com/>), funded by the European Union Research and Innovation programme, advancing personalized drug treatment in patients with CKD.

This announcement contains inside information under the UK Market Abuse Regulation. The person responsible for arranging for the release of this announcement on behalf of the Company is James McCulloch, CEO.

For further information, please contact:

Renalytix plc

James McCulloch, CEO

www.renalytix.com

Via Walbrook PR

Stifel (Nominated Adviser, Joint Broker)

Alex Price / Nicholas Moore / Nick Harland / Samira Essebiyea

Tel: 020 7710 7600

Investec Bank plc (Joint Broker)

Gary Clarence / Shalin Bhamra

Tel: 020 7597 4000

Walbrook PR Limited

Paul McManus / Alice Woodings

Tel: 020 7933 8780 or renalytix@walbrookpr.com

Mob: 07980 541 893 / 07407 804 654

CapComm Partners

Peter DeNardo

Tel: 415-389-6400 or investors@renalytix.com

About Renalytix

Renalytix (NASDAQ: RNLX) (LSE: RENX) is an artificial intelligence enabled in-vitro diagnostics and laboratory services company that is the global founder and leader in the field of bioprognosis™ for kidney health. In late 2023, our kidneyintelX.dkd test was recognized as the first and only FDA-authorized prognostic test to enable early-stage CKD (stages 1-3b) risk assessment for progressive decline in kidney function in T2D patients. By understanding how disease will progress, patients and clinicians can take action earlier to improve outcomes and reduce overall health system costs. For more information, visit www.renalytix.com.

Steno Diabetes Center

Steno Diabetes Center Copenhagen is an internationally leading diabetes hospital, established in 1932. Steno Diabetes Center Copenhagen is based in Greater Copenhagen, as a public-private partnership between the Capital Region of Denmark and the Novo Nordisk Foundation, which is supported by a donation of 0,4 billion Euro from Novo Nordisk Foundation the Novo Nordisk Foundation. Steno Diabetes Center Copenhagen's purpose is not only to improve the quality of the diabetes treatment in the Capital Region, but also nationally and globally to contribute to the development of new models for a value-based healthcare system. Steno Diabetes Center Copenhagen is Scandinavia's largest diabetes hospital.

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, the Company's expectations regarding the timing and outcome of regulatory and reimbursement decisions, the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery and improve patient outcomes, the Company's expectations and guidance related to partnerships, testing volumes and revenue for future periods, the Company's expectations regarding the Company's ability to obtain and maintain intellectual property protection for its diagnostic products and the Company's ability to operate its business without infringing on the intellectual property rights of others, and the forecast of the Company's cash runway and the implementation and potential for additional financing activities and cost-saving initiatives. Words such as "anticipates," "believes," "estimates," "expects," "intends," "plans," "seeks," "indicates" and other similar expressions are intended to identify forward-looking statements. By their nature, forward-looking statements are inherently predictive, speculative and involve risks, uncertainties and assumptions that could cause actual results, financial condition, performance, developments, or achievements to differ materially from those expressed or implied by the forward-looking statements. Accordingly, the Company may not actually achieve the plans and objectives disclosed in the forward-looking statements, and you should not place undue reliance on the Company's 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, uncertainties and assumptions relate to factors that are beyond the Company's ability to control or estimate precisely, such as changes in taxation or fiscal policy, future market conditions, currency fluctuations, the behaviour of other market participants, the actions of governments or governmental regulators, or other risk factors, such as changes in the political, social and regulatory framework in which the Company operates or in economic or technological trends or conditions, including inflation, recession and consumer confidence, on a global, regional or national basis. These risks 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; the Company has only recently commercially launched KidneyIntelX; and risks relating to the impact on the Company's business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in the Company's filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of its annual report on Form 10-K filed with the SEC on September 28, 2023, the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 filed with the SEC on November 14, 2023, the Company's Quarterly Report on Form 10-Q for the quarter ended December 31, 2024 filed with the SEC on February 14, 2024 and other filings the Company makes with the SEC from time to time. All information in this press release is as of the date of the release, and the Company undertakes 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. In particular, but without prejudice to the generality of the above, no representation or warranty is given, and no responsibility or liability is accepted, either as to the achievement or reasonableness of any future projections, forecasts, estimates or statements as to any prospects or future returns contained or referred to in this press release or in relation to the basis or assumptions underlying such projections, forecasts, estimates or statements. Except as required by applicable law or regulation, each of the Company and the Joint Brokers expressly disclaim any obligation or undertaking to release any updates or revisions to these forward-looking statements whether as a result of new information, future events or otherwise.