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Trinity Biotech Announces Acquisition of Metabolomics Diagnostics to Grow Presence in Maternal Health Market

-Metabolomics Diagnostics, a deep-tech machine learning diagnostic platform developer, has developed an innovative test, PrePsia, to accurately predict the risk of preeclampsia in pregnant women-

-The PrePsia test can predict preeclampsia risk as early as in the 12th week of pregnancy, allowing for early interventions to prevent serious health issues for mothers and their babies-

-PrePsia will be commercialized in the U.S. market in 2025 through Trinity Biotech's New York-based Immco reference laboratory -

DUBLIN, Ireland (September 24, 2024) - Trinity Biotech plc (Nasdaq: TRIB), a commercial-stage biotechnology company focused on human diagnostics and diabetes management solutions, including wearable biosensors, today announced that it has acquired privately held Metabolomics Diagnostics, an Irish deep-tech company, specialized in the development of novel biomarker-based diagnostic solutions for complex diseases. The deal values Metabolomics Diagnostics with an enterprise value of approximately \$1.3 million with the consideration consisting of just over 270,000 Trinity Biotech plc's ADS with the balance of consideration being in cash and the assumption of liabilities.

This acquisition provides Trinity Biotech with a strategically important deep-tech platform of mass spectrometry combined with machine learning powered bioinformatics. Trinity Biotech will initially leverage its New York State-based Immco reference laboratory to rapidly commercialise the PrePsia test in the U.S. market, while examining the launch of this test in international markets. This technology platform represents another long-term growth driver alongside Trinity Biotech's continuous glucose monitoring (CGM) technology.

The Company intends to manufacture the PrePsia test reagents in-house and commercialise the test in its New York State Department of Health-certified Immco diagnostic reference laboratory, with first revenues from preeclampsia testing expected in 2025. Given the late stage of development of PrePsia, and significant synergies with Trinity Biotech's existing capabilities and infrastructure, the additional investment for commercialisation in 2025 is expected to be limited.

“Human diagnostics is often regarded as one of the areas of healthcare that can most benefit from advances in artificial intelligence and machine learning. As such, it is strategically important for Trinity Biotech to have a proprietary, integrated human diagnostics platform which combines advanced biomarker analyses with machine learning to deliver better diagnostics for patients. More broadly, this acquisition aligns with our strategy of combining Trinity’s established capabilities – in this case, our manufacturing expertise and New York State Department of Health-certified Immco reference laboratory – with cutting edge technologies such as Metabolomics Diagnostics’ analytical, machine learning and bioinformatics expertise to address large scale, urgent and important clinical issues, in this case in maternal and fetal health,” said John Gillard, President and Chief Executive Officer, Trinity Biotech. “Additionally, this low-cost transaction is structured to become quickly accretive to our overall franchise.”

Dr Robin Tuytten will join the Trinity Biotech management team and continue to serve as Director of Metabolomic Diagnostics. Dr Tuytten stated: “Trinity Biotech has the ideal manufacturing and regulatory expertise to bring our innovative maternal risk screening diagnostics platform to the market. Through Trinity Biotech’s U.S.-based Immco reference laboratory, we look forward to accelerating the introduction of our potentially life-saving preeclampsia risk screening technology to the U.S. market and addressing the acute maternal health crisis while strengthening Trinity’s internal diagnostic innovation pipeline.”

According to the Centers for Disease Control and Prevention in the U.S. (CDC), there were 3.6 million births in the U.S. in 2023. Preeclampsia is a frequently occurring maternal health issue, impacting up to 5% of pregnancies, which can cause serious illness or death in affected mothers and babies. The condition is generally diagnosed by the presence of high blood pressure and measurements of kidney function and blood work at 20 weeks of pregnancy. Due to the lack of meaningful therapeutic interventions, a preeclampsia diagnosis can lead to a medically induced delivery of the baby. As a consequence, approximately 30% of preeclampsia diagnoses result in premature deliveries.

In peer-reviewed papers co-authored with leading Key Opinion Leaders, the Metabolomics Diagnostics proprietary PrePsia technology has been shown to deliver improved prediction of pre-term preeclampsia risk at week 12 of pregnancy, a timeframe which would allow for the prescription of effective medication which can significantly reduce the risk of often serious health issues for mothers and their babies. For details of publications, see <https://metabolomicdiagnostics.com/our-research/>.

The Metabolomics Diagnostics PrePsia test uses an analytical technique known as mass spectrometry to identify the presence of tens of metabolites in a blood sample. A powerful machine learning-driven algorithm then combines the result of this metabolomic testing with other patient-specific clinical information to deliver a personalised preeclampsia risk score that can be used to determine the need for additional medical intervention. Trinity plans to leverage this cutting-edge technology to develop other important diagnostic tests in the maternal health sector.

Forward-Looking Statements

This release includes statements that constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 (the “Reform Act”), including but not limited to statements related to Trinity Biotech’s cash position, financial resources and potential for future growth, market acceptance and penetration of new or planned product offerings, and future recurring revenues and results of operations. Trinity Biotech claims the protection of the safe-harbor for forward-looking statements contained in the Reform Act. These forward-looking statements are often characterized by the terms “may,” “believes,” “projects,” “expects,” “anticipates,” or words of similar import, and do not reflect historical facts. Specific forward-looking statements contained in this release may be affected by risks and uncertainties, including, but not limited to, our ability to capitalize on our purchase of the assets of Waveform, our continued listing on the Nasdaq Stock Market, our ability to achieve profitable operations in the future, the impact of the spread of COVID-19 and its variants, potential excess inventory levels and inventory imbalances at the company’s distributors, losses or system failures with respect to Trinity Biotech’s facilities or manufacturing operations, the effect of exchange rate fluctuations on international operations, fluctuations in quarterly operating results, dependence on suppliers, the market acceptance of Trinity Biotech’s products and services, the continuing development of its products, required government approvals, risks associated with manufacturing and distributing its products on a commercial scale free of defects, risks related to the introduction of new instruments manufactured by third parties, risks associated with competing in the human diagnostic market, risks related to the protection of Trinity Biotech’s intellectual property or claims of infringement of intellectual property asserted by third parties and risks related to condition of the United States economy and other risks detailed under “Risk Factors” in Trinity Biotech’s annual report on Form 20-F for the fiscal year ended December 31, 2023 and Trinity Biotech’s other periodic reports filed from time to time with the United States Securities and Exchange Commission. Forward-looking statements speak only as of the date the statements were made. Trinity Biotech does not undertake and specifically disclaims any obligation to update any forward-looking statements.

About Trinity Biotech

Trinity Biotech is a commercial stage biotechnology company focused on human diagnostics and diabetes management solutions, including wearable biosensors. The Company develops, acquires, manufactures and markets diagnostic systems, including both reagents and instrumentation, for the point-of-care and clinical laboratory segments of the diagnostic market and has recently entered the wearable biosensor industry, with the acquisition of the biosensor assets of Waveform Technologies Inc. and intends to develop a range of biosensor devices and related services, starting with a continuous glucose monitoring product. Our products are used to detect infectious diseases and to quantify the level of Haemoglobin A1c and other chemistry parameters in serum, plasma and whole blood. Trinity Biotech sells direct in the United States and through a network of international distributors and strategic partners in over 75 countries worldwide. For further information, please see the Company's website: www.trinitybiotech.com.