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Prolight takes clear steps toward commercialization of the Psyros™ POC system

Prolight continues to make steady progress toward finalizing the Psyros Point-of-Care System toward market readiness. Following the successful delivery of the commercial prototypes and subsequent testing at Guy's and St Thomas' Hospital earlier in 2025, the company is now finalizing a series of design and manufacturing enhancements to optimise assembly and reproducibility ahead of the clinical performance study. This represents a critical investment in time and effort to ensure long-term product robustness and scalability. The final stages of incorporating these design refinements are underway, and procurement of long-lead manufacturing components has already commenced.

The ramp up of cartridge manufacturing continues to deliver encouraging results with our partner FlexMedical Solutions. Current efforts are focused on optimising the manufacturing process parameters for the pilot line, enabling consistent cartridge production for verification and validation. In addition, the reagent production process is undergoing validation to secure a dependable supply of qualified materials for pilot manufacturing. Although this work is time-consuming, our goal remains to reach assay design freeze during the current quarter. Following the assay design freeze and final instrument design, pilot production of the instruments will commence with our partner ITL (Integrated Technologies Ltd).

Results from the recent pre-clinical study have been very well received by commercial partners, who are highly impressed by the pace at which the Psyro system is advancing through its development stages. This positive feedback reinforces confidence in both the system's technical potential and its strong market relevance.

The strong results from the pre-clinical validation studies were achieved using only a small subset of biobank and whole blood patient samples from St Thomas'. This efficient use of materials enables us to preserve significant resources, with the remaining samples now available to support the final verification and validation stages. The final system verification will confirm the robustness, user-friendliness, and reproducibility of the platform ahead of the clinical performance study.

Strong progress is also being made in preparation for the clinical performance study, supported by our contract research organization, MDx. Site qualification activities are in progress across selected hospitals in Europe. Given the complexity of cardiac troponin studies in emergency department settings, Prolight will strategically choose to partner with hospitals that possess substantial experience in studies of this scale and complexity. This complexity further underpins the importance of detailed planning and preparation for the study to ensure seamless execution.

Thanks to its unique value proposition, the Psyros system continues to generate positive feedback from both potential commercial partners and end users. Unlike existing high-sensitivity point-of-care systems that rely on costly and complex cartridges, Psyros uniquely combines laboratory grade analytical performance with a simplified, low-cost consumable design whilst enabling a truly portable system that can be used in a diverse range of settings. This differentiation positions Prolight to address a substantial unmet need in the global point-of-care cardiac diagnostics market as well as in many more clinical areas.

By investing the time and resources now to optimize the system design for manufacturing, Prolight is laying the foundation for a successful market launch and long-term commercial growth. The company remains confident that the Psyros system's combination of performance, cost-effectiveness, and scalability continues to represent a compelling opportunity to create significant shareholder value in the rapidly growing global market for point-of-care diagnostics.

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