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Key parallel advances in cartridge manufacturing and instrument development for the Psyros™ platform

Over recent weeks, Prolight has continued to make important progress in the development of the Psyros platform. Progress in cartridge manufacturing scale-up, alongside continued refinement of the instrument design, further strengthens the platform as the company prepares for the commercial launch.

CARTRIDGE MANUFACTURING SCALE-UP

Production of the Psyros cartridge has now entered a more advanced phase of scale-up. The company continues to optimise its manufacturing capability with the intention of supporting initial launch volumes and, subject to further validation and operational ramp-up, scaling capacity to support volumes of in excess of one million cartridges per annum as demand develops.

The state-of-the-art manufacturing line for Psyros cartridges is highly modular and designed to support phased and efficient expansion. This flexibility underpins Prolight's strategy to combine very high analytical sensitivity with a low production cost, supporting a cost profile suitable for broad point-of-care adoption.

The cartridge design has been developed specifically for large-scale manufacturing without compromising performance. This approach enables competitive pricing and supports broad global adoption across both established and emerging markets.

COMPLETION OF THE INSTRUMENT DESIGN AND PREPARATION FOR PILOT MANUFACTURING

In parallel, Prolight has completed a pre-clinical evaluation of 30 prototype instruments. The results supported the system's technical performance and enabled the identification of a limited number of targeted hardware improvements aimed at supporting long-term product reliability and scalable manufacturing.

Working closely with the with Prolight's instrument development partner ITL, these improvements are now being finalized into the instrument design. Completion of the design is expected to reduce risks associated with transfer to manufacturing and to support consistent, high-quality production as volume increases.

The final instrument design is being prepared for transfer into pilot manufacturing. To support the planned development timeline, orders for certain long lead-time components have already been placed.

NEXT STEPS

The next steps will involve the manufacture of pilot instruments using the final components and production processes. These instruments will represent the commercial product and will be used for internal verification and validation activities, including design freeze, as well as in the forthcoming clinical performance study. These are the final and decisive steps in the near term ahead of commercial launch.

Further background information and interviews with members of the Prolight team will be published shortly by BioStock.

Ulf Bladin, CEO Prolight Diagnostics