

PROLIGHT ACHIEVES SIGNIFICANT MILESTONE WITH ARRIVAL OF FIRST PSYROS™ COMMERCIAL PROTOTYPE INSTRUMENTS

Prolight is proud to announce the arrival of the first of thirty full commercial prototype instruments of its groundbreaking Psyros™ Point of Care (POC) system from its development partner G&H IITL. This lays the foundation for the pre-validation study and subsequent clinical performance study in 2025, in-line with the timeline towards commercial launch in 2026.

“This means that we will have a significant number of commercial prototypes up and running at our laboratories in December, which is a massive technical milestone. After passing our rigorous stress-testing, these commercial prototypes will be used in the pre-validation study for the final fine-tuning of the Psyros test and platform. This will ensure the final commercial design is robust ahead of the transfer to production and the subsequent clinical performance study next year”, said Paul Monaghan, Head of Engineering at Prolight.

“We are eager to begin testing with these commercial prototypes which will be used in our pre-validation study from which we expect the first results in Q1 2025. Those results will minimize risks and help ensure an optimal outcome for the subsequent multi-centre clinical performance study in 2025. Thus, we are in line with the overriding timeline, where the clinical performance study results will provide the basis for a IVDR regulatory application, paving the way for the commercial launch of our high-sensitivity troponin test in 2026,” said Ulf Bladin, CEO of Prolight.

In total, the pre-validation study comprises of approximately 1,200 frozen biobank plasma samples and fresh whole blood samples from approximately 120 cardiac patients at St. Thomas’ Hospital in London, UK.

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About Us

Prolight Diagnostics AB develops innovative Point-of-Care (POC) systems. These are small, portable instruments and disposable cartridges for performing in-vitro diagnostic (IVD) tests from a drop of blood.

We want to offer the foremost POC systems on the market for quick, reliable diagnosis of acute events. Our launch product will be for the measurement of troponin, to aid in the rule-in and rule-out of myocardial infarction.

The company’s share is traded on the NGM Nordic SME marketplace, under the ticker PRLD.

Attachments

Prolight achieves significant milestone with arrival of first Psyros™ commercial prototype instruments