PROLIGHT
Diagnostics you can count on

# Investor letter October 2, 2023

## Interview with Karl Bullen, COO at Prolight Diagnostics

**- Everything is developing according to plan**

**What made you join the Prolight Diagnostics group?**
The track history of the founders of the Psyros™ technology initially hooked my interest. This was reinforced when I first met the development team at the facilities in Sandwich. The ability of the team to demonstrate the capability of the technology at such an early stage of development (less than 6 months into the program) was compelling. What quickly became clear to me was that this was a simple yet uniquely powerful technology, with real potential to be produced at a low cost. This was supported by an experienced team who had the know-how and drive to bring a disruptive technology to market. It was at that point that I decided I could not miss the opportunity to be part of this journey.

**The organization recently moved to a refurbished office, including your own laboratories. How do you think these new facilities will contribute to your continued success?**
As you can see from our photos, we now have a modern office space that has been tailored exactly to our needs. The additional laboratory space has allowed us to expand R&D operations as we accelerate our development program. We have also established a dedicated manufacturing development line that is being used to optimize the manufacturing processes that will be used for pilot production.

## How would you describe the culture in the organisation today?

We have been able to attract an excellent team of competent and highly experienced staff to expand the organisation. The culture is one of excellence, coupled with teamwork, and a strong belief in our goals. Although we are still a small organisation, we are lean, efficient and extremely effective. Everyone is proud that we have delivered on our internal milestones and are confident that everything is progressing according to plan.

## What are you and the team focusing on right now?

There is significant activity across multiple work streams. The three key focus areas for the development program right now are: number one - developing our Quality Management System (QMS) to obtain ISO 13485 accreditation for the development of IVD devices. This is a significant milestone on our path to regulatory certification of the Psyros™ POC system. The second focus area is continuing the development of our high-sensitivity troponin assay, and our preferred antibody combinations are now being optimized. The third focus area is completion of useability studies for the cartridge design and proposed system workflows within the emergency department (ED). These studies provide powerful insights to ensure that the product not only meets stringent regulatory requirements, but also satisfies the needs of end users in a variety of settings.

## How many different types of prototypes will you develop with ITL to get to the final instrument?

The exact number of prototypes and sub-modules to develop in order to get to a commercial instrument ready for clinical validation can vary. In general, the process looks as follows: we will work together with ITL to produce a batch of alpha prototypes to fine tune the design. Next, we will produce beta prototypes to be used for regulatory compliance testing, evaluation, and verification. When these processes are complete, we will transfer to the pilot manufacturing line to produce the first commercial instruments ready for validation and clinical performance studies. We have strong internal experience to accomplish the above processes and I have great confidence that we will successfully deliver in collaboration with ITL.

## Will you manufacture the cartridge in-house or will you outsource to a contract manufacturer?

This is a critical decision, to ensure that we achieve the lowest cost of goods, coupled with the most cost-effective manufacturing overheads. We are still evaluating both options and are awaiting proposals from contract manufacturers before we take that decision.

## During the 2023 AACC* Annual Scientific Meeting + Clinical Lab Expo in July you initiated contacts with potential partners. How are discussions progressing and can you disclose any company names?

The AACC meeting is the foremost international congress for IVD companies. We met hundreds of participants and received huge levels of interest at the meeting. This positive feedback confirmed that our proprietary, digital POC technology may be the start of a paradigm shift for POC testing. With our breakthrough technology comes the ability to develop new ultra-sensitive POC tests that are currently only available in specialized laboratories for clinical diagnostics. Given the positive response we received at AACC we are now accelerating our business development activities. However, these activities involve the engagement of many stakeholders in each company and the process is time consuming. All conversations are regulated under mutual NDA and therefore I may not disclose any company names.

* AACC is now becoming the Association for Diagnostic & Laboratory Medicine (ADLM)

Lastly we want to inform that the congress Japanese Association of Clinical Laboratory Systems (JACLaS) will take place during October 6-8, 2023 in Yokohama Japan. TTP (The Technology Partnership) will participate and showcase a concept of the POC system Microflex in their booth. For more info please see: https://www.ttp.com/events/jaclas-expo-2023/.