

Investor Letter September 30, 2024



Product in development phase.
Design and specification may change in the final product.

The rapid and cost-effective development of our unique proprietary digital point-of-care (POC) system, Psyros™, continues at an unwavering pace toward market approval and commercial launch. Psyros represents a groundbreaking ultra-sensitive technology with the potential to create substantial economic value for both the company and our shareholders. Therefore, it is vital that we ensure every step in the current final phase of this process is executed with strong governance and meticulous accuracy.

In addition to our ongoing rapid development progress in Q3, our team has also engaged in several important external activities, detailed below.

ADLM (ASSOCIATION FOR DIAGNOSTICS & LABORATORY MEDICINE)

At the end of July and early August, Prolight showcased the Psyros™ system at ADLM, one of the world's largest and most significant diagnostics congresses held in Chicago, USA. We were proud to present the latest prototype of our commercial instrument and the cartridge designed for high-sensitivity troponin assays. The feedback we received was overwhelmingly positive, leading to many constructive discussions. As a result, we now have a long list of high-potential partners.



This year, we observed an even greater interest from major diagnostic companies compared to previous years, which we attribute to our rapid advancements over the past 12 months, during which we have:

Finalized commercial cartridge design.

- Simple low part count design, designed for manufacture at large scale to ensure a competitive low cost of goods.
- Contains all the reagents required to complete the test with dried cartridge chemistry to avoid the complexity and cost of expensive liquid reagents/blister packs.

Appointed Flex Medical Solutions as manufacturing partner for our cartridge.

- Flex Medical Solutions is a specialist

contract manufacturer of medical equipment with existing, fully validated facilities.

Selected MDx CRO for the clinical performance studies for the high sensitive troponin test.

- MDx has a reputation for excellence, comprehensive research capabilities and specialising in regulatory compliance.

Demonstrated robust performance in the low single digit ng/L range.

- Incorporated internal cartridge quality controls, ensuring every test result is validated.

Received a prestigious British grant of SEK 17 million for the development of Psyros POC system.

- The grant is an external endorsement of the potential of our proprietary, single-molecule-counting POC technology.
- The grant enables us to set up a pre-validation study at St Thomas' Hospital in London, UK to secure an optimal outcome of the clinical performance study.

Even after ADLM, our list of potential partners continues to grow. We anticipate that interest will further increase as we move into verification and validation activities and begin generating initial clinical data from our upcoming pre-validation study at St. Thomas' Hospital. Please see the separate paragraph below for more details.

Read more about the positive feedback at ADLM: <https://www.biostock.se/2024/08/prolight-diagnostics-receives-positive-feedback-at-adlm-congress/>

PRE-VALIDATION STUDIES

A pre-validation study will be initiated on the Psyros POC platform using whole blood from approximately 120 patients presenting with chest pain and suspected myocardial infarction at St. Thomas' Hospital in London, UK.

Additionally, around 700 blood samples will be tested and analyzed from a biobank of healthy patients, along with approximately 400 blood samples from patients with chest pain, of which 200 have confirmed myocardial infarction. The data generated from these studies will be used for final optimization of the assay and the POC platform.

The results will minimize risks and help ensure an optimal outcome for the clinical performance study in 2025, which is expected to increase interest from potential partners in the Psyros POC system.



London St Thomas' Hospital is located opposite the Palace of Westminster.

BUSINESS REVIEW AT FLEX MEDICAL SOLUTIONS

During the second quarter we completed the design for the disposable cartridge intended for commercial use with our contract manufacturing partner, Flex Medical Solutions (FMS). The simplicity of the design not only allows for a highly competitive cost but also enables the outsourcing of manufacturing.

The cartridge consists of only a few components, designed for large-scale production to ensure a competitively low production cost. Another important competitive advantage is that it contains all the necessary reagents to complete the test without the need for complex and costly liquid reagents and blister packaging. Additionally, the cartridge is ergonomically designed for ease of use and is compatible with both venous and capillary blood, as well as plasma samples. Another competitive advantage is multiplexing, meaning that multiple biomarkers can be tested on a single cartridge with as little as one drop of blood.

In September, Prolight conducted a business review at FMS. The review included a progress update and an inspection of the pilot cartridge manufacturing line and associated support facilities.

“It was exciting to see the significant progress FMS has made over the last few months. With building works now complete, it was great to see the first wave of production equipment being installed” said COO Karl Bullen.

“We are very proud of our facilities and our team and as such it is always a privilege to host our clients. The dedicated Prolight production suite is really taking shape and we are excited to take receipt of the remaining manufacturing equipment in the coming months” said Murray Whyte, CTO.

The pilot line at FMS is being commissioned to support the regulatory approvals including the clinical performance study and volumes for commercial launch. With the ability to produce hundreds of thousands of cartridges at a competitive cost of goods, the technologies and processes being developed by FMS are designed to be scalable with future high levels of automation, thus enabling a swift transition to full-scale commercial production.



Team Prolight and Team Flex Medical Solutions

2024 CARDIAC MARKERS DIALOGUE MEETING

The prestigious event, Cardiac Markers Dialogue Meeting, on 26th September and 27th September 2024 in Glasgow, UK brought together global key opinion leaders in cardiology including leading researchers and healthcare professionals, to discuss advances in cardiac biomarker diagnostics and their implications for patient care.

The 2024 Cardiac Markers Dialogue Meeting provided an invaluable platform for Prolight to showcase its single molecule counting POC platform Psyros™ and engage in dialogue with experts. It was also an opportunity to gain insight to state of the art on critical topics such as advances in biomarker research, their use in early detection of cardiac events, and the integration of new technologies in clinical practice.

“Our commitment to advancing rapid diagnosis of potential myocardial infarction at the point of care aligns perfectly with one of the goals of the Cardiac Markers Dialogue Meeting. We engaged with many fellow professionals, shared information about our proprietary POC technology and received feedback that once more confirmed that Psyros POC system will significantly contribute to improved outcomes for patients worldwide” said Dr Aileen McGettrick, CSO of Prolight.

The Cardiac Markers Dialogue Meeting featured keynote speakers, panel discussions, and workshops designed to enhance understanding and application of cardiac markers in clinical practice

For more information about the 2024 Cardiac Markers Dialogue Meeting, please visit Cardiac Marker Dialogues (cmdmeeting.org.uk).



Toby Greenfield (Scientist), Aileen McGettrick (CSO) and Steve Ross (CTO)

Emergers published an updated analysis on Prolight Diagnostics

End of August Emergers published an updated analysis on Prolight Diagnostics reaffirming a justified value of 1.1-1.2 SEK per share.

Read the full article: https://www.emergers.se/prolight_e/



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Warrants of series TO7

From October 7 to October 18, 2024, the opportunity to exercise the TO7 subscription warrants for shares in Prolight Diagnostics will be available. We hope that as many TO7 warrant holders as possible will participate, allowing us to accelerate our efforts. More information about the TO7 warrants will soon be available on our homepage www.prolightdx.com

We look forward to finalizing the development of our proprietary, innovative POC technology Psyros™ into a commercial product, thereby creating value for healthcare, patients, and our shareholders.