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Abionic: Vision, Key Products and Strategic Direction

Abionic SA has appointed Patrick Pestalozzi as CEO. With three decades of global experience in management consulting and entrepreneurship, Patrick has been instrumental in creating and developing deep-tech ventures. His diverse healthcare background positions him to lead Abionic's next growth phase. ICU Management & Practice interviewed Patrick about his vision for the company.

What is your vision for Abionic?

I took over the leadership of Abionic last April after Nicolas and Iwan, Abionic's co-founders, decided it was time for new blood to steer the company across its next development milestones, including deploying a promising new sepsis biomarker in the U.S.

Building innovative medical technologies has been the DNA of Abionic since its inception in 2010. The winner of multiple industry awards, including "Swiss MedTech of the Year" in 2023, Abionic was founded on the vision that nanofluidics could transform diagnostic testing by delivering lab-quality results in minutes across a range of biomarkers. After a decade of R&D that pushed the boundaries of science and technology, our flagship **abioSCOPE®**, a near-patient rapid diagnostic platform, was released for commercial use.

I was recruited to transform an effective R&D start-up into a nimble commercial organisation capable of delivering our portfolio of rapid tests at the point of need. One particular asset in our portfolio I am focusing on is **PSP** (Pancreatic Stone Protein), an emerging sepsis biomarker that indicates the onset of sepsis 24-48h earlier than current standards. The timely and early detection of sepsis is critical to initiate optimal treatment protocols and increase the odds of patient survival.

Sepsis is an ominous health threat affecting 50 million patients worldwide and the cause of 11 million deaths, or 1 in 5 global deaths (WHO 2024). Our mission is to address the poorly met need for quick & reliable sepsis identification worldwide.

What are key strategic changes to be implemented?

Following a successful multicentric study in Europe which paved the way to our IVDR certification in Q3 '22, we completed a major multi-site study in the U.S. in 2023 and swiftly filed our FDA 510(k) submission in early 2024. These studies and 50+ peer-reviewed publications confirm the high potential PSP holds to address the poorly met need for quick and reliable sepsis recognition in emergency and critical care settings.

My mandate for 2025 is to lay the groundwork to enable Abionic's successful market entry into the United States, where sepsis strikes 1.7M patients, causes at least 350,000 deaths, and costs $38B annually (CDC 2023). That includes building a sustainable commercial capability to ensure we can scale our operations and successfully deploy multiple critical pilots with partner hospitals from coast to coast.

How will Abionic evolve within the ICU segment?

PSP may be of the utmost clinical utility in Burn ICUs where accurate biomarkers are needed to identify septic cases before patient deterioration. Severely burned patients often present an inherent state of hyperinflammation, which frequently conceals septic events, which in turn often delays the initiation of targeted intensive care therapy.

In a monocentric observational study completed in 2021 (Klein et al.), the authors concluded that PSP was able to differentiate between septic and non-septic patients during acute burn care. Its steep rise (up to 72 hours before clear clinical deterioration) provides physicians with valuable clinical insights and actionable information to initiate optimal treatment, resulting in reduced mortality and costs.

However, the clinical utility of PSP is not limited to acute settings but holds tremendous potential in upstream workflows, such as emergency department (ED) triage, or even beyond hospital settings in retirement communities, as a screening tool enabling the early identification of community-acquired sepsis.

Are there any strategic partnerships to be considered?

Indeed, considering the resources and capabilities required to successfully enter a new market, we are currently evaluating alternative GTM options and will consider strategic partnerships to distribute & commercialise the abioSCOPE and the world's fastest sepsis test in the United States.

For other geographies, our strategy is rather simple and follows a proven and tested playbook: we've established a wide network of partners in 50+ geographies and work closely to deliver our solutions across emergency and critical care settings worldwide.

Abionic is known for its rapid diagnostic tools. What new technological advancements are in the pipeline to stay ahead of the competition?

We are continuously innovating and developing our technology. Some key advancements include enhanced sensitivity for detecting concentrations as low as a few picograms per millilitre, optimising functional multiplexing, expanding our test portfolio into other testing areas and developing a comprehensive data analysis capability.

Is AI an option in Abionic's products?

The integration of artificial intelligence and machine learning frameworks (AI/ML) is inevitable and takes us a step closer to a future of "predictive" diagnostics.

Where can Abionic's rapid testing solutions play a role in optimised workflow management?

Optimising hospital workflows is the key to unlocking operational efficiencies and financial savings, beyond improving patient outcomes first and foremost. Emergency departments, intensive care units, ambulance services, remote care and even primary care clinics or retirement communities can benefit from easy-to-use solutions that provide lab-quality results within minutes. The abioSCOPE easily integrates into hospital workflows and can become a major go-to solution to address the need for rapid and accurate results in time-sensitive cases.

What are your strategies for expanding Abionic's market presence? What markets enjoy priority?

Our core portfolio products are currently used across 20 reference sites in Europe, the Middle East, Latin America, and Asia. For 2025, we are planning to work hand-in-hand with our distributors to expand our market reach with our early adopters in Eastern Europe, Greece, and Italy. For larger healthcare markets such as France and Germany, we will deploy a direct-to-market approach to ensure PSP is positioned across key settings in ED & ICUs.

Do you see regulatory challenges as a problem when entering markets?

Regulatory pathways remain a challenge for most small organisations vying to bring innovation at the point of need. We invest a substantial part of our operational budgets, ensuring we fully comply with increasingly complex and demanding requirements.

What potential partnerships or collaborations are on the horizon?

Our corporate and business development objectives are still being defined, but I can share that we expect to broaden the field of use of our technology in the coming months. Considering the resources and capabilities required for a successful market entry, we are currently evaluating strategic alternatives to leverage our technology assets and deploy the world's fastest sepsis test in the U.S.

What areas of unmet medical needs are you targeting today?

The timely identification and recognition of sepsis remains a major pain point across emergency and acute care settings. Our PSP assay, which runs exclusively on our abioSCOPE platform, integrates into existing hospital workflows and delivers optimal clinical utility in settings where time-to-recognition is key to improving patient outcomes.

What advantages of cost-effectiveness are met for healthcare providers and patients?

Focusing, for example, on sepsis, our diagnostic tools enable early and accurate detection, reduce the need for extensive testing and prolonged hospital stays, improve patient outcomes, and consequently lower overall healthcare costs.

How do you balance the development of innovative products with cost restraints?

Our product managers and commercial teams scan the market to identify disease areas and viable use cases where time-to-recognition is a must-have, and our rapid Turn-Around-Time Kis a winning feature which confers a clear and distinctive competitive advantage. For example, we recently developed a ferritin test on the basis of a use-case, which confirmed that speed and accuracy were key drivers to rule-in/out donors at the point of collection.

Where do you stand with clinical trials, results and market approvals?

In the sepsis field, we have completed a European multicentre observational study with 14 sites and a U.S. multicentre observational study with six sites, leading to IVDR certification in Europe and a pending 510(k) in the U.S. Besides 50+ publications that evaluated PSP as a sepsis marker, we also have ongoing post-market performance studies which bring continuous insights and strengthen our scientific and clinical evidence backbone.

What are the most significant challenges facing the industry today?

From labour shortages to rising treatment costs, cybersecurity issues, rising regulatory compliance, or even patient safety, our industry is at risk of failing its primary mission - to provide the best care to all. As a scale-up medical technology, besides having to deftly navigate complex international regulatory and reimbursement pathways, competing against established healthcare incumbents on an equal footing makes delivering innovation at the point of need daunting. To ensure the flow of innovative solutions to address current and future unmet needs continues unabated, we should consider new regulatory and buy-side pathways to facilitate market access.

How is Abionic contributing?

Our flagship abioSCOPE delivers lab-quality results from a drop of blood (50 µl) within minutes and integrates seamlessly into existing hospital workflows. In time-sensitive emergencies such as sepsis, ordering a PSP screening assay can accelerate the time-to-recognition and trigger a faster initiation of optimal treatment protocols and increase the odds of patient survival - in terms of improved patient outcomes and streamlined healthcare, I cannot think of a better contribution. Furthermore, as decentralised care becomes more common in the near future, I can imagine that enabling Remote Patient Monitoring (RPM) functions will rely on a consumer version of the abioSCOPE and other such IVD technologies to provide simple and practical testing at home.

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