

Our mission is to make the body's chemistry easily accessible for improving personal wellbeing in health and disease — anytime, anywhere. Contact Charles Versaggi, Ph.D. Versaggi Biocommunications 415/806-6039 <u>cv@versaggibio.com</u>

profusa

How are you?

Typically, once a year we see a physician and get blood tests to answer the perennial question: *How are you*? But in between such spot checks, we don't actually know what is going on in our body — from understanding our aerobic fitness, to knowing our blood electrolytes during intense exercise, to managing our glucose metabolism as a person with diabetes. Depending on one's age, lifestyle, and health state, the list of such questions goes on and on.

While many of us may struggle to maintain our fitness, others are faced with diabetes and other chronic diseases that affect more than 70 million individuals in the U.S., accounting for more than 75 percent of our healthcare expenditures — that's \$2 trillion (National Health Council). The World Health Organization has warned that the burden of chronic diseases worldwide is rapidly increasing and will account for almost three-quarters of all deaths by 2020. This is putting the nation's healthcare under even more pressures, with greater calls for consumers to become more health conscious, and the key driver for why the mobile health market alone is expected to reach \$41 billion by 2020.

To lose weight, improve athletic performance, or manage our general health, one of the biggest challenges is finding the right tools to measure, monitor and analyze our progress. While fitness trackers and other wearables provide insights into our heart rate, respiration and other physical measures, they don't provide information on the most important aspect of our health: our body's chemistry.

What if there was a better way of knowing how you're doing - how you're really doing?

Tissue-integrated Biosensors

Profusa is leading the development of a new generation of tissue-integrated biosensors that empowers the individual with the ability to monitor their unique body chemistry in unprecedented ways to transform the management of personal health and disease. Overcoming the body's response to foreign material for long-term use, our technology promises to be the holy grail of real-time biochemical detection through the development of bioengineered sensors that become one with the body to detect and continuously transmit actionable, medical-grade data for personal and medical use.

Rather than being isolated from the body, Profusa's patented biosensors work fully integrated within the body's tissue — without any metal device or electronics — functioning for years while overcoming the effects of local inflammation or rejection. Combining smart technology on the outside of the body with advanced chemistry on the inside, our biosensors will provide immediate, actionable information to individuals, physicians, and public health practitioners. Aimed at being a leading force in the digital disruption of medicine, Profusa's real-time biosensors are poised to revolutionize healthcare, yielding significantly more insights into one's overall health status and performance than tracking physical parameters alone.

Profusa's biosensors will have many applications for consumer health and wellness, as well as the management of chronic diseases such as peripheral artery disease (PAD), diabetes, and chronic obstructive pulmonary disease (COPD). The company's first product, the *Lumee™ Oxygen Platform,* is now available in Europe for monitoring of tissue-oxygen perfusion in the management of PAD and chronic wounds. Profusa is also developing continuous biosensors for glucose, as well as evaluating biosensors for lactate, carbon dioxide, pH, and other body chemistries.

A clinical trial of the *Lumee Oxygen Platform* is being conducted in Europe to demonstrate its utility in the management of *critical limb ischemia (CLI)*, a severe form of PAD that markedly reduces blood flow to the extremities (hands, feet and legs) to the point of severe pain from skin ulcers, sores, or gangrene. CLI is a very severe condition that needs immediate comprehensive treatment by a vascular surgeon or vascular specialist.

These and other applications of Profusa's biosensors have the potential to dramatically change healthcare by paving the way for decentralization of healthcare delivery and shifting the focus to preventative health. In addition to developing its own product pipeline, the company is assessing partners to commercialize its technology for other applications.

Profusa's Technology

Breaking the Biocompatibility Barrier

Profusa's unique bioengineering approach overcomes the largest hurdle in long-term use of biosensors in the body: the *foreign body response*. Approximately 5 mm long and 500 microns in diameter, each tiny biosensor is a soft, flexible fiber designed to be biologically compatible with the body's tissues for long-term monitoring for years while overcoming the effects of local inflammation or rejection.

Tissue-integrating Scaffold

Providing medical-grade data, the biosensor is made of a porous "smart gel" that mimics the 3D microenvironment of cells. The smart gel is linked to a light-emitting molecule that emits a fluorescent signal in the presence of one or more body chemicals such as oxygen, glucose, lactate, or other biomarkers.

Optical Reader

Adhered to the skin's surface or held by hand, a separate optical reader is used to read the fluorescent signal from the embedded biosensor. The reader sends excitation light through the skin to the biosensor, which then emits fluorescent light proportional to the amount of the biochemical measured.

Adaptable Form Factor for Consumer and Medical Applications

Profusa's technology platform enables the development of biosensor systems with a variety of form factors serving consumer as well as medical applications for continuous monitoring of body chemicals. Results from the optical reader can be transmitted to a smart phone application that allows the user to make actionable decisions, from improving their general health and well-being, to taking their athleticism to another level, or managing a chronic disease such as diabetes or COPD. Data can be shared securely via HIPAA-compliant digital networks with healthcare providers and public health analysts conducting longitudinal studies.

How It Works



Excitation light in the reader.

on the skin surface from the reader and reaches the biosensor under the skin.



2. The biosensor is embedded with a biochemical that emits fluorescent light proportional to the chemical of interest in the tissue.









3. Fluorescent signals from the biosensor travel to the surface of the skin where they are captured by the reader. Results can be uploaded to a smart phone and the Internet for an encrypted personal record and historical tracking.

Lumee Oxygen Platform for Peripheral Artery Disease

Profusa's first clinical offering, the *Lumee Oxygen Platform,* is designed to report reliable tissue oxygen levels at various regions of interest, both acutely and long-term. It may be used in applications where monitoring of compromised tissue is beneficial, such as PAD that results in narrowing of blood vessels and reduced blood flow to the lower limbs; chronic wounds (diabetic ulcers, pressure sores) that do not heal properly; and reconstructive surgery.

PAD is a disease in which plaque buildup obstructs arteries in the leg, causing cramping pain during exertion (claudication) or in more advanced cases, gangrene, non-healing wounds that require surgical intervention or amputation. PAD affects 202 million people worldwide, 27 million who live in Europe and North America, with an annual economic burden of more than \$74 billion in the U.S. alone.

The *Lumee Oxygen Platform* may help salvage limbs by providing the medical practitioner with a new way to continuously measure tissue oxygen levels in the ischemic limb before, during, and after treatment, enabling appropriate therapy to be administered in a timely fashion before advanced symptoms appear. Results obtained from the first-in-human study suggested that the *Lumee Oxygen Platform* could report local tissue oxygen levels during PAD surgical intervention as well as post-operatively for 28 days, and posed a low risk to patients during the study (*J. Vasc. Surg., June 2015, Volume 61:6, 1501-10*).

Note: The Lumee Oxygen Platform is not cleared for marketing by the U.S. Food and Drug Administration, and is an Investigational Device Limited by Federal Law to Investigational Use Only.

Management team

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