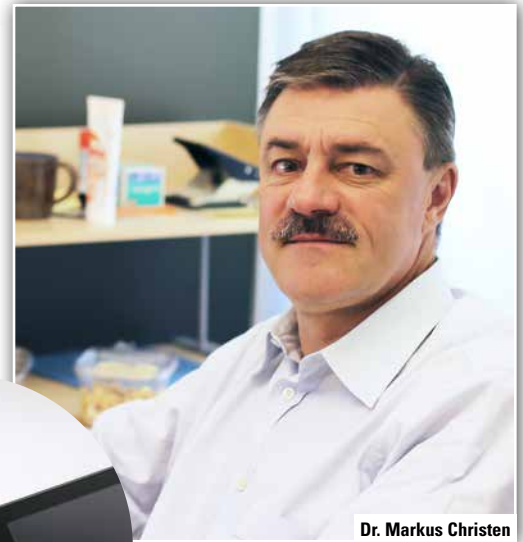# From Smart Pills to
DIGITAL MEDICINES

Markus Christen, Ph.D., Senior VP, Global Development, Proteus Digital Health, talks about the company's smart pill technology, which has the potential to lead to a new therapeutic category of products: digital medicines.

Dr. Markus Christen

D igital technology is transforming just about everything in healthcare. Proteus Digital Health has a vision of a connected health system that revolves around its "smart pill" and health feedback system.

Proteus Digital Health is creating a new category of products, services, and data systems that have the potential to significantly improve the effectiveness of existing pharmaceutical treatments. Called digital medicines, these new pharmaceuticals integrate medicines with ingestible, wearable, mobile, and cloud computing and delivery solutions.

But that is not all. The company aims to create an entire offering around this technology that takes a different approach to health and, hopefully, leads to significant cost savings for the healthcare system, says Markus Christen, Ph.D., senior VP, global development, Proteus Digital Health.

Proteus, a private company, was formed in 2001 and has raised more than $300 million in funding. The company's digital feedback system provides an unprecedented view into an individual's personal health choices and physiologic responses. The digital health feedback system includes a sensor on a pill that, when swallowed with a medication, transmits the time of medication ingestion and communicates with a wearable patch that measures heart rate, activity, and other information.

"It is a tiny microchip, which sits in the center of the pill," Dr. Christen says. "It is made of inert materials, and when those materials come into contact with the stomach, it starts to send a signal indicating that a medication has been ingested."

He says the microchip operates like a battery that encodes a unique code.

"That code is received by a tiny patch, which is worn on the skin and reports information on the patient's mobility, heart rate, etc.," he says. "That information is sent via Bluetooth to a mobile device. From there the information goes to our central databank and from there it goes to whomever the patient selects to receive the data."

The ingestible sensor received European regulatory approval (CE Mark) in August 2010 and U.S. FDA market clearance as a medical device for co-ingested applications in July 2012.

The company is working with integrated health systems to incorporate the technology

Proteus's health feedback system includes wearable and ingestible sensors that work together to gather information about medication-taking and activity.

to address medication adherence.

Proteus conducted a pilot program in hypertension with the UK's National Health Service to manage a group of patients with uncontrolled hypertension; 164 patients were put on the Proteus system for two weeks. Proteus was able to identify medication taking and adherence patterns and blood pressure readings and physiological measures and provided diagnostic insight to differentiate patients needing therapy change, medication adherence support, further clinical testing, or those controlled on current therapy.

Through measurement and feedback, the company was able to identify that 54% of patients were controlled with the existing therapy when they took their medicines regularly and these patients still needed encouragement and counsel to continue with their therapy and derive the full outcome. About 23% of the patients needed a new therapy because they were unresponsive even when adherent to therapy.

Proteus is now working with four regions of the UK to integrate the system into the NHS infrastructure and demonstrate value to the individual and health system. Dr. Christen also says the company is developing commerical pilot programs with integrated health systems in the United States.

Pharma Partnerships

Proteus Digital Health has been working to create a new category of products and offerings with the potential to significantly improve the effectiveness of existing pharmaceutical treatments. Proteus is working with a number of pharmaceutical companies, including Otsuka Pharmaceutical Co. and Novartis, to address several therapeutic areas, including CNS and transplant rejection.

The Otsuka collaboration aims to develop commercial products in two defined therapeutic areas of high unmet medical need. Otsuka has

also been granted a non-exclusive license to use Proteus technology in its clinical research and development activities.

The agreement with Novartis aims to develop and commercialize pharmaceutical products that incorporate Proteus' sensor-based technologies in the field of organ transplantation.

"We are working with one company in the areas of depression and bipolar disease," Dr. Christen says. "With another, we are also working in the area of mental health, including the integration of the technology into an Alzheimer's drug. And we're currently working on a portfolio of metabolic disease management drugs, blood pressure lowering drugs, diuretics, lipid lowering drugs, and diabetes drugs."

Proteus Digital Health is also collaborating with Oracle to incorporate the digital health feedback system into clinical trials. The companies are working together to provide clinical investigators with the ability to measure information about medication ingestion, dose timing, and associated physiologic response continuously and precisely for patients enrolled in clinical trials. The companies are integrating Proteus' digital health feedback system with Oracle's clinical trial products — Oracle Health Sciences InForm, Oracle Life Sciences Data Hub and Oracle Argus Safety — using the Oracle Health Sciences Cloud.

Dr. Christen says the use of the technology in the clinical trials space is exciting.

"We are expecting that there will be a huge amount of quantitative savings and improvements in drug discovery and development because companies will know for the first time that patients are consistently taking the drug," Dr. Christen says. "They don't have to make assumptions any more about what happens when patients go home after leaving a clinical site. We can provide very actionable insights into efficacy and toxicity. We'll be able to monitor and address adherence. We will also have the potential to lower study costs and possibly see the need for fewer numbers of patients for trials." (PV)

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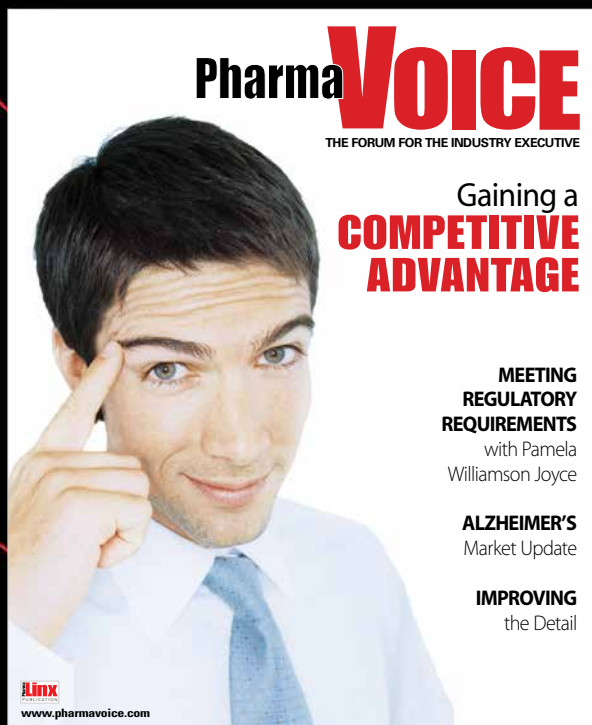
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