

Claros Diagnostics Inc.

A revolution in diagnostics

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Contact: Michael J. Magliochetti, PhD,
President & CEO

Industry Segment: *In Vitro* Diagnostics

Business: Handheld, point-of-care
diagnostic instrument for urology

Founded: 2004

Founders: Vincent Linder, PhD, CTO;
Samuel Sia, PhD, Chair, Scientific
Advisory Board (Columbia University);
David Steinmiller, COO; George
Whitesides, PhD, Advisor (Harvard
University)

Employees: 4

Financing to Date: \$7.8 million

Investors: Oxford Bioscience Partners;
Bioventures Investors; Accelerated
Technologies Partners; Commons
Capital

Board of Directors: Jeffrey T. Barnes (Oxford
Bioscience Partners); Jack Davis (Hillside
Capital Management); Marc Goldberg
(Bioventures Investors); Michael Lytton
(Oxford Bioscience Partners); Michael J.
Magliochetti; Caroline Popper, MD
(Popper & Co.); David Steinmiller

Medical/Scientific Advisory Board: Samuel
Sia; Peter T. Scardino, MD (Memorial
Sloan-Kettering Cancer Center); Alan J.
Wein, MD (University of Pennsylvania
Medical Center); E. Darracott Vaughan,
Jr., MD (Cornell University); Stephen P.
Dretler, MD (Massachusetts General
Hospital and Harvard Medical School);
Georg Bartsch, MD, (Innsbruck Medical
University, Austria)

Point-of-care diagnostic kits typically consist of test strips that the health care provider tips with a swab of sputum or finger-stick of blood and inserts into a handheld device for near-immediate answers to yes-no, high-low questions. They're simple to use, cheap, fast, reliable within an acceptable range, and disposable. For the more quantitative and definitive antibody screening needed in most situations, though, a more substantial amount of patient blood must be sent out to a diagnostic lab, and hours or days later results from an enzyme-linked immunosorbent assay (ELISA) arrive. These tests are comparatively complex, expensive, and time consuming; only centralized diagnostic facilities can manage sample handling and the cost

of instruments and reagents. A point-of-care diagnostic instrument that had the advantages of a test-strip device in terms of ease of use and rapid results along with ELISA-like capabilities for major diseases would circumscribe diagnosis routinely within the course of a patient visit. That would revolutionize diagnostic practices. **Claros Diagnostics Inc.** has developed just such a device that it hopes to sell to doctors' offices, initially for urological applications, beginning in 2009.

The company's handheld immunoassay system incorporates a lab-on-a-chip configuration to produce high-performance quantitative laboratory blood test results with the ease of use of rapid qualitative diagnostic strip tests. The technology consists of a disposable

cassette (approximately the size of a credit card, with preloaded reagents) capable of testing for multiple disease markers simultaneously and a handheld hardware unit similar in size and simplicity to an over-the-counter glucose meter. The Claros device requires a finger-stick of blood and provides results in minutes. The simplicity of the fully loaded disposable cassette and subsequent ease of use alleviates the regulatory burden on the physician or hospital, which for a quantitative point-of-care test is required to have qualified staff draw blood, subsequently spin down the collected sample to attain serum, and utilize the necessary reagents to conduct the test.

The Claros technology was developed in the **Harvard University** laboratory of George Whitesides, who is famous for his work in the fabrication of nanostructures, microfluidics systems, microelectromechanical systems, and three-dimensional structures. His intellectual property has already spun out into the founding of more than a half-dozen companies, including Genzyme, Surface Logix, and Theravance. His group is noted for synthesizing and characterizing structurally well-defined organic surfaces (especially using self-assembled monolayers) and solids, and for using these assemblies to study physical properties such as wettability and biocompatibility. Applying this knowledge base to lab-on-a-chip assemblies, he and company co-founders Vincent Linder, who is now Claros' CTO, Samuel Sia, now on the faculty of Columbia University and chair of the company's Scientific Advisory Board, and David Steinmiller, now COO, developed proprietary amplification chemistry coupled with microfluidics that allows quantification of protein levels using inexpensive, off-the-shelf

detection technology. They developed novel microfluidic handling methods to permit operation of multiplexed assays. Most important for point-of-care end users, this enables a disposable lab-on-a-chip cassette to be constructed in plastic by state-of-the-art injection molding techniques, providing significant cost advantage over any other



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—Michael J. Magliochetti

quantitative point-of-care system on the market or, claims president and CEO Michael J. Magliochetti, in development.

Magliochetti was an entrepreneur-in-residence in the offices of Oxford Bioscience Partners, scouting his next gig after the sale of orthopedics-focused RMH, where he had been CEO until its sale to Otto Bock. He previously had been CEO of HemaMetrics, a private blood-monitoring and diagnostic company, and before that he had been CEO of UroSurge, which specializes in products for the urology market. He has also held senior positions with the medical device company Haemonetics and the polymer products company Delta Surprenant. All those experiences coalesced while he was serving on the advisory board for the Pediatric New Technology Initiatives Group of Boston Children’s Hospital, when a fellow board member told him about the diagnostic lab-on-a-chip in development at Whitesides’ lab.

The Whitesides group planned an initial focus on the sexually transmitted disease and developing world market,

but Magliochetti thought the urology market would be a more attractive first target. He knew that there are approximately 20 million digital rectal exams performed annually in the US on men over the age of 50 by urologists and general practitioners, most often as part of their annual physical examination screening for qualitative prostate size and any abnormalities. These exams are coupled with a blood draw and subsequent battery of blood panel tests, which include measurement of prostate specific antigen (PSA) along with a panel of other markers. The data from these tests drive the decision by urologists to perform approximately one million prostate biopsies annually on patients (all of whom will have their PSA levels retested for confirmation prior to biopsy). Postprostate cancer treatment follow-up is conducted for approximately 2.5 million US men today. More than 30 million PSA tests are performed annually in the US alone. The PSA testing market totals more than \$1 billion dollars annually. Moving those PSA-level tests out of the diagnostic lab and into the clinician’s office would prove highly attractive to practitioners, who could capture diagnostic revenues now being sent to outside labs, and also to insurers, who would happily reimburse the lower cost. (See “Molecular Diagnostics—From Tools to Tests,” IN VIVO, May 2006.)

For these reasons, Magliochetti believes the urology market will likely prove easier to move to a new platform than the other markets previously considered. “I raised the urological application to the forefront with a focus on a diagnostic panel for urological cancers,” he says. “It is an excellent space to validate the technology.” However, he believes the device will have wide application, including cardiovascular, gynecology, infectious diseases, and even veterinary medicine. He also thinks emerging biomarkers coupled with therapies will make the device an attractive adjunct to treatments, especially in comparison with the \$100,000 tabletop ELISA instruments plus expensive trained personnel it will compete against.

The company already has a disposable prototype. “There’s a lot of technology packed into it—microfluidics along with the chemistry needed to yield sensitivity equivalent to a centralized lab,” Magliochetti says. “From the perspective of an end user, the technology will appear as simple as a glucose test for diabetic monitoring. It’s plug-and-play with a finger-stick of whole blood.”

However, scaling up to manufacturing poses substantial hurdles to ensure the necessary sensitivity in each assembly. There’s little room for error in diagnostics. “I’ve been there before,” he says. “Just because you can get 10 disposables to work, that’s different from getting 10,000 out. It’s a challenge, but we feel really good about it.”

Magliochetti expects the company to be ready to apply for 510(k) clearance from the Food and Drug Administration in the first quarter of 2009. The company closed on a Series A \$7.8 million financing in mid-January, with Oxford taking the lead. Magliochetti believes that will be enough money to carry the company through its FDA filing. By the end of this year, he expects the company’s current full-time staff of four to reach as many as 10.

With numerous potential clinical applications for its device, Magliochetti expects the company will be very attractive to potential partners. “We’ve seen a tremendous amount of M&A activity in the diagnostics space, with several large players such as **Siemens AG, General Electric Co.**, and others articulating and acting upon a strategy for point-of-care diagnostics.” He points to well-known large diagnostic players such as Bayer Diagnostics and **Abbott Laboratories Inc.**’s diagnostics divisions being acquired (by Siemens and GE, respectively). “This activity further complements the existing market leaders such as **Roche, Becton Dickinson & Co.**, Fisher Scientific International [now **Thermo Fisher Scientific Inc.**] and **bioMerieux SA**, all of which will recognize the bandwidth of Claros’ technology, which offers the potential to transform the diagnostics landscape.”—**Marc Wortman**