

START-UP



Windhover's Review of Emerging Medical Ventures

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Clarity Medical Systems Inc.

Point and shoot 3-D optical imaging

5775 West Las Positas Boulevard
Pleasanton, CA 94588

Phone: (925) 463-7984

Fax: (925) 251-0078

Web Site: www.claritymsi.com

Contact: Keith L. Mullowney, Chairman,
President & CEO

Industry Segment: Ophthalmic Imaging
Devices

Business: Integrated optics and image
archiving

Founded: 1994 as Massie Laboratories
Inc.; restart as Clarity in 2005

Founders: Bert Massie

Employees: 70

Financing to date: \$22 million

Investors: Cockrell Interests Inc.; Research
Development Foundation of Texas

Board of Directors: Keith Mullowney;
Robert Hatcher (Cockrell Interests); Evan
Melrose, MD (PTV Sciences); Jeffrey
Otten (JRO Ventures Inc., ex-Stentor);
Thomas Loarie (Mercator MedSystems
Inc., ex-KeraVision)

Ophthalmology has become a fertile field for device innovation, at least on the therapeutic side. Favorable demographics—many eye diseases are related to aging—have encouraged start-up companies and their investors to explore non-drug solutions to numerous undermet clinical needs. (See “An Early Peek at Glaucoma Devices,” *START-UP*, February 2006); “Devices for Age-Related Macular Degeneration,” *START-UP*, February 2005; “Presbyopia at Arm’s Length,” *START-UP*, July 2003, “From The Foundry: An Incubator Focused on Ophthalmology,” *START-UP*, December 2005.)

But devices for diagnosing eye disorders are not attracting the same

level of interest. For all intents and purposes, ophthalmologists and optometrists are using the same screening and imaging technologies that they have used for the past half century.

Clarity Medical Systems Inc. intends to disrupt the status quo with a single platform that physicians can use to screen, evaluate, and one day potentially treat eye disease. Unlike current optical imaging instruments that allow physicians to view the eye in three dimensions but image it only in two, CMSI’s technology enables wide-angle stereodigital 3-D images that capture exactly what physicians see when they look in the eye. The digital

images captured by CMSI’s technology will allow doctors to accurately track changes in the eye over time. The system also has advanced clinical data management capabilities, including PACS (picture archiving and communications system). Images taken with CMSI’s technology form the basis of an electronic medical record that can be transferred digitally to off-site specialists for remote evaluation.

CMSI is a restart of Massie Laboratories Inc., founded in 1994 as a government contract research organization. In 1997, Massie Labs migrated to ophthalmology following its acquisition of a promising pediatric screening technology developed at the **University of Southern California**. Over the next eight years, under the leadership of founder Bert Massie, the company developed and commercialized the *RetCam* system for pediatric ocular imaging, which is now sold in 37 countries.

In the late 1990s, Massie Labs began to develop new technology for the much larger adult ophthalmic market, for detecting and monitoring treatment of such disorders as glaucoma, wet and dry age-related macular degeneration, diabetic retinopathy, presbyopia, and cataracts.

Eager to accelerate progress on its adult platform, dubbed *P2*, CMSI’s investors decided last year to restart the company. In August 2005, they hired an experienced chairman, president, & CEO, Keith Mullowney, who had just retired as chairman of Thermage Inc., the successful aesthetic device company he

co-founded in 1996. Mullowney immediately added \$8 million from existing investors to CMSI's coffers; more than half of the \$14 million the company had raised up to that point.

Mullowney has put that money to work. In the past 12 months, CMSI has instituted an ISO-certified quality program, has hit sales targets for *RetCam* for the first time in almost five years, and has increased its headcount from 37 to 70 by adding engineers across all pertinent disciplines—electrical, mechanical, software, and optics. CMSI has also completed a prototype and received 510(k) clearance on its *P2* adult screening system, in preparation for anticipated US launch in 2007.

To understand the promise of CMSI's technology, you first need to understand the current state of the art in optical imaging, Mullowney says. The primary tools that ophthalmologists and optometrists use for imaging eyes are the slit lamp—a microscope with an attached light for imaging the front of eye—and the binocular indirect ophthalmoscope (BIO)—for viewing the back of the eye. Both are analog instruments that provide physicians with a 3-D view of what is happening in the eye, but methods to record that data—whether expensive fundus cameras that require extensively trained, skilled operators; stereodigital imaging technologies from companies like **Optos PLC** and **Visual Pathways Inc.** (See “*Visual Pathways Inc.*,” *START-UP September 2001*); or most commonly, the physicians own drawing in the patient's chart—are two-dimensional and don't fully depict the condition of the eye's interior.

P2 will be the first truly digital, integrated platform for ocular imaging, says Mullowney. It combines the functions of the slit lamp and BIO with a CCD camera, and it can simultaneously acquire 3-D visual data from the front and back of the eye, without dilation. The unit's small footprint allows it be placed at the point of care in the examination room, so there is no need to transfer patients to the back office for imaging.

The automated point-and-shoot technology is designed for operation by nonskilled technicians. It takes just 40 milliseconds to obtain an image, Mullowney says.

The registered 3-D images accurately depict current eye conditions and will



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improve diagnostic accuracy, he states. They will also enable earlier detection and management of potentially blinding disorders. As a patient's electronic clinical record builds over time, physicians will be able to objectively compare volumetric and topographic changes in the eye to monitor disease progression and response to drug treatment. According to Mullowney, use of electronic medical records in ophthalmology is already on the rise despite the limited two-dimensional resolution; for example, 35% of retinal specialists today use EMRs. He believes that *P2* will accelerate this adoption and that ophthalmologists and optometrists—CMSI's targeted customers—will be eager to migrate to CMSI's platform because it will improve patient care.

It will have economic benefits for doctors as well. “Current technologies are not only old, they are isolated,” says Mullowney. *P2*'s integrated digital hub will increase throughput because less time will be spent in shuffling patients from the exam room to the imaging room. And since lower-salaried technicians can operate *P2*, doctors will be free to see more patients. Doctors will also be able to capture more

billable procedures, due to the range of functions available with *P2* that are not available with current technology, and will decrease their reliance on expensive ophthalmic photographers. Use of *P2* will be reimbursable under existing CPT codes for ophthalmic imaging.

CMSI's customers can expect a rapid return on their investment, Mullowney asserts. The company plans to offer the *P2* hardware on a rental basis, with monthly licensing fees for software and data storage. CMSI estimates that the \$5,000 per month fee for a typical practice will net it close to \$12,000 in additional monthly revenues from existing customers, starting with the first month of use. Because it combines many functions into one device, “the cost of our technology and its various integrated components is less than individual equipment buys,” says Mullowney.

As for its own revenues, Mullowney conservatively estimates that based on placing just one unit in just 15% of the 240,000 user sites worldwide *P2* represents a \$4 billion opportunity.

Although the company's primary focus is on moving *P2* to market, Mullowney also intends to grow the company's *RetCam* pediatric ocular imaging business. It is currently in use at 350 sites in 37 countries, including many major US children's hospitals such as Boston Children's, St. Jude's, and the Lucile Packard Children's Hospital at Stanford University.

RetCam has become the gold standard for diagnosing retinoblastoma, an uncommon but devastating pediatric eye cancer, says Mullowney. It also diagnoses shaken baby syndrome, and retinopathy of prematurity (ROP), a condition in which posterior vasculature of the eye develops too aggressively. ROP can be treated by laser therapy if detected in time. If left untreated, it leads to retinal detachment and a good chance of blindness. Some 600 children in the US each year lose their vision to ROP, and more than 1,500 develop treatment-warranted disease.

This March, the American Academy

of Pediatrics, the American Academy of Ophthalmology, and the American Association for Pediatric Ophthalmology issued new guidelines recommending that all premature infants born before 32 weeks and weighing less than 3.5 pounds be screened for the disease. This translates into 80,000 babies who must be screened annually in the US. Moreover, the guidelines call for screening every 72 hours for high-risk children.

Attrition in the ranks of retinal specialists, caused by low reimbursements and malpractice threats, makes adherence to these guidelines a real challenge, says Mullaney. Therein lies an expanded opportunity for *RetCam* as the basis for a telemedicine approach to ROP screening. Nurses in neonatal intensive care units (NICUs) can take images using *RetCam* and transfer them via electronic networks for evaluation by one of the dwindling number of ROP specialists.

CMSI has evidence that telemedicine screening is as effective as a bedside diagnosis for ROP: an

independent study at six centers comparing remote screening with *RetCam* to physician screening with BIO show that *RetCam* was 100% specific and 97% sensitive for detecting ROP. More important, says Mullaney, "*RetCam* found clinically significant ROP one to two weeks earlier than the other method." Networks for remote ROP screening with *RetCam* are springing up across the country, including a five-hospital network recently launched by Stanford.

These networks will drive dramatic expansion of the business, Mullaney believes. *RetCam*, currently installed at approximately 350 of the 2,500 NICUs worldwide, is bringing in \$6 million annually; the tip of the iceberg for what CMSI believes is a potential \$500 million worldwide opportunity.

Clarity Medical currently has five issued and two pending patents that cover its hardware, optics, and software algorithms. In addition, one of its patents covers the technology next up in its pipeline: adding a laser fiber to *P2* to support therapeutic

applications. Such a device could be used to treat such disorders as diabetic retinopathy or AMD, much more easily than current lasers that require the operator to target with a slit lamp while aiming the laser. Within the next year, CMSI intends to partner the therapeutic application. The company will also use partners for PACS capabilities.

Everything else is done in-house. Clarity Medical is in the midst of raising a \$25 million Series C round being managed by SG Cowen. The proceeds will go toward manufacturing scale-up and product launch of *P2*, a product that Mullaney thinks is destined for clinical and commercial success.

"There have been three transforming technologies in medical imaging in the past 15 years: MRI, CT and PACS," he says. "They all helped move radiology from analog, two-dimensional x-rays to three-dimensional electronic visual records. He believes that Clarity Medical Systems has a compelling opportunity to do the same in eye care.—Nancy Dvorin