

Financing Demonstrates Faith in Surgical Sleep Apnea Treatment

San Diego Business Journal



[1]

Marcelo Lima

IMTHERA MEDICAL INC.

CEO: Marcelo Lima.

Financial data: Not disclosed.

No. of local employees: Six.

Investors: Generated private funds of \$8.2 million from high-net-worth individuals in three rounds.

Headquarters: Carmel Valley.

Year founded: 2004.

Company description: Develops a neurostimulation medical device for the treatment of obstructive sleep apnea.

A San Diego device maker has put to bed more than \$8 million of funding to test and develop a pacemakerlike device that could help some sleep apnea sufferers get relief without relying on air masks.

ImThera Medical Inc., which was founded in 2004, is putting the money to good use by developing a surgical procedure that implants a neurostimulation medical device in a sleep-deprived persons chest, which connects to the tongue. The idea is to stop the tongue and throat muscles from relaxing so much that they collapse and

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impede breathing while a person is sleeping, said Marcelo Lima, the companys co-founder and chief executive officer and a 25-year veteran of the medical device industry.

The company continues to have success on the funding front to develop prototype equipment and pay engineers. Its next goal is to complete an additional placement of venture funding at the end of this month, said Lima.

Its all private funds from high-net-worth individuals, he said, adding that the majority of investors are from the U.S., but include backers from Australia, Belgium, France and Germany.

These are very challenging patients, said Lima, referring to an estimated 1.5 million noncompliant sleep apnea patients in the U.S. who cannot use continuous positive airway pressure, or CPAP, machines on the market. But before ImThera can bring these patients relief in the U.S., it has a pilot study under way at a hospital in Belgium, where 12 patients have had the device implanted. Nearly 80 percent have reported a dramatic decrease in sleep interruptions. Lima estimates 500,000 patients in Europe could potentially benefit from the technology.

ImThera will concentrate on the Western European countries to roll out the product, ramp up sales and revenue, and then attract further investment to fund trials in the U.S., which are expected to begin this year at hospital sites in San Diego, Chicago, Denver and Oklahoma City.

Major Medical Concern

Sleep apnea is a major concern among medical researchers who suspect that the condition plays a bigger role in chronic disease. In 2003, the National Institutes of Health, or NIH, pinpointed sleep apnea as a major cause of hypertension, which affects one in four American adults. Sleep apnea occurs when a persons upper airways collapse, often repeatedly, during sleep.

While going after a niche market, ImThera has ambitious plans to be a force in the next few years with its technology, which has competitors working in the same space, but with decidedly different approaches. Apnex Medical Inc. of St. Paul, Minn., and Inspire Medical Systems of Minneapolis are also working in the field of hypoglossal nerve stimulation.

Lima said the Carmel Valley business employs six staff members with extensive experience in medical devices and neurostimulation. ImTheras sleep therapy system, known as aura6000, uses a technique called targeted hypoglossal neurostimulation as another way of providing therapy for patients not helped by traditional treatments such as CPAP.

Major device makers such as San Diegos ResMed have been addressing the issue through design improvements and monitoring techniques, but compliance remains one of the biggest challenges in treating sleep apnea, which is estimated to affect more than 18 million Americans, according to the NIH.

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ImTheras solution requires patients to undergo a 60-minute surgery to implant the device. The patient then turns the rechargeable device on or off. Once it is introduced to the U.S. market, Lima projects a cost of \$20,000 for the device and an estimated \$9,000 to \$12,000 for the surgery. The procedure calls for the involvement of two physicians. First, an ear, nose and throat surgeon will implant the device and then a pulmonologist or sleep physician will adjust it.

Advancing to Next Level

Dr. Terence Davidson, ImTheras chief medical officer and a head and neck surgery professor at UC San Diego, is hopeful that the device will receive approval by the U.S. Food and Drug Administration in two to three years.

The challenge at that point will be to secure the buy-in from health payers.

The reimbursement process will be a problem at first because insurance companies will be nervous about paying the bill, said Davidson, who will be monitoring the data from the U.S. study sites.

The private payers will be looking closely at how the technology scores with the Centers for Medicare & Medicaid Services, the federal agency that administers Medicare programs and works with state governments to administer Medicaid programs, said Davidson.

I dont foresee long-term problems that will blunt its success as an effective alternative to treat some sleep apnea patients, said Davidson.

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