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Andante Medical Devices, Inc. is Bringing to Market their Unique SmartStep® Broad Technology Platform that Interacts with Orthopedic, Neurological Trauma and Parkinson's Patients and Uses Audio and Visual Biofeedback to help Retrain the Brain to Re-Learn How to Walk Correctly

Healthcare Medical Devices (Private)

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Reynald Bonmati
Chairman/CEO

BIO:

Mr. Bonmati has served as President/CEO of Andante Medical Devices, Inc. since October 1, 2008 and Chairman/CEO since July 20, 2010. Mr. Bonmati is also serving as Chairman of the Board of Directors of Orthometrix, Inc., a distributor of peripheral Quantitative Computed Tomography systems (pQCT®) for bone and muscle research, and as Presi-

dent of Bones L.L.C. a private investment firm. Mr. Bonmati has thirty years of experience in the founding and management of companies in the Life Sciences. He has participated in the development of a number of companies in the Life Sciences, including DNAX Research Institute of Molecular & Cellular Biology (now part of Schering Plough, Inc.), Chiron Corporation (now owned by Novartis), Codon Corporation (became Berlex Biosciences and is now part of Bayer AG), Columbia Laboratories, Inc. (NasdaqGM: CBRX), and Norland (now part of Cooper Surgical, the women's healthcare unit of the Cooper Companies – NYSE:COO). Mr. Bonmati holds B.S. and M.S. degrees in Chemical Engineering from Institut National Supérieur de Chimie Industrielle in France, an M.S. degree in Petrochemical Engineering from Ecole Nationale Supérieure du Pétrole et des Moteurs in France, as well as an M.B.A. from University of Paris. In 1977, he moved to the United States where he settled with his family and became a citizen. He started his first company in 1980.

Company Profile:

Andante Medical Devices, Inc. develops, manufactures, markets and services patented Functional Feedback Therapy (FFT) systems that use audio and visual biofeedback to help retrain the brain to get rid of bad habits following a trauma and to quickly relearn how to walk correctly again. The Andante team consists of experts in rehabilitative medicine, biomedical engineering, and physical therapy.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOFCFO Magazine

CEOFCFO: Mr. Bonmati, you have a long history in the industry; what is special for you about Andante Medical Devices?

Mr. Bonmati: Andante attracted my attention 4 years ago when it was developing the SmartStep® in Israel for orthopedic rehabilitation at the hospital, particularly in sports medicine. At that time, Andante was starting to look at the US market. Because of my history in the field, I recognized that SmartStep was more than a device. It was a broad technology platform, capable of producing a number of devices for a number of large markets. I personally invested in the company and led its restructuring as a US entity. I expanded its reach from orthopedic rehabilitation to the larger neurological rehabilitation market; from the hospital market to the much larger homecare market; and from the Israeli market to the US and Japanese markets. Hopefully soon, we will expand to China and Europe. For example, in the US alone, at \$500 million total market potential for the SmartStep Clinic model and \$10 million consumable potential per year, the hospital market is large. However, several segments of the homecare market are as large or even larger, and per year. Just to name a few, the stroke market is \$2 billion per year in SmartStep potential sales. The hip and knee surgery market is \$500 million per year in rental and the orthopedic injuries market is over \$1 billion in rental, in the US alone.

CEOFCO: Would you tell us about SmartStep?

Mr. Bonmati: SmartStep is a patented technology platform, initially used for gait training. It is used to help patients who have suffered from an orthopedic or neurological trauma, get back to a normal life faster, and not only at the hospital, but also at home. We are talking about quickly regaining normal mobility after a sports injury, hip and knee surgery or replacement, but also a stroke. There is also Parkinson's and eventually Diabetic Neuropathy. Unlike current technologies that are all passive and more expensive, the SmartStep is unique in a sense that it interacts with a patient and uses audio and visual biofeedback to help retrain the brain to re-learn how to walk correctly, and also provide motivation to help speed up recovery.

CEOFCO: What are the methods that have been used traditionally for these applications and why is the SmartStep superior?

Mr. Bonmati: Despite the growing impact on our lives, this is a sector that has seen very little innovation over the years. Current methods are subjective. They use qualitative verbal instruction by physical therapists, mirrors, bathroom scales and the famous "calibrated eyeball" of the physical therapist. The current methods of measuring progress are passive and have no biofeedback to retrain the brain. They cost between two and twenty times more than the SmartStep. In addition, they are not mobile, so you cannot bring them into the home environment.

CEOFCO: How widespread is the use today, where is the most use of the SmartStep and how do you reach the markets that are not using it today?

Mr. Bonmati: Despite the low awareness of the market as we did not have a US sales force until this year, we have sold the SmartStep Clinic model to over 100 prominent hospitals in the US alone, to both their ortho trauma and neuro trauma departments. We also received a contract from the Veteran's Administration to supply the 153 VA hospitals in the US. We received market approval in Japan last

year and we have now shipped over 100 units to Japan. We also expect market approval in China by the end of the year. Regarding Europe, we already have the CE mark and have sold the SmartStep passively to clinicians who came to the US for a trade show and we plan an active approach shortly. We are also looking for a European strategic partner to speed up market access. In the US, we started renting a sales force in February of this year (2012). Our partner is called MedPro. It distributes half a dozen devices from much larger companies in the US like Smith & Nephew, Welch Allyn and Schiller. It is the first time that MedPro teamed up with a small company like Andante. They love the device and they think that it can penetrate not only the hospital, but also the long term care market.

CEOFCO: When professionals are introduced to Andante Medical De-

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vices, do they get it right away and understand immediately how it works or do they need convincing?

Mr. Bonmati: When you see the unit and try the unit, it is very easy to appreciate immediately its impact, particularly on the patient. When we show the unit to a group of therapists, we usually ask them to bring a patient and most of the time they bring the most difficult patient for them to treat and the patient usually wants to take the SmartStep home. The concept sells itself and since it is a very small machine, it is easy to transport, so demonstrations are easy to make. If you are talking about the medical community, it is well documented that the overwhelming reason for failures in lower limb surgery like the hip and the knee, of which there are one million hip and knee replacement surgeries in the US per year, have nothing to do with the surgeon or the implant. It usually has to do with the lack of compliance of the patient with the limited weight bearing instructions of

the surgeon post surgery. The orthopedic surgeon will prescribe increasing weight bearing on the affected limb post surgery. Say you can only put 30% of your body weight for a week, and then increase that to 60% and so on until putting your full weight on the affected limb. Not enough weight can be as bad as too much weight too soon. There is no device that can help the clinician determine, with minimum reliability, whether the patients are actually putting the 30% weight as prescribed by the doctor. Orthopedic surgeons have bought the SmartStep Clinic model and demonstrated the medical necessity of the SmartStep to enforce such compliance. The first study was published by Yale earlier this year and two more hospital studies are in the process of being published. The next step is to do a home study, where the focus would be to secure reimbursement for the prescription by orthopedic surgeons of the use of the SmartStep to protect their surgery. A reimbursement of \$600 over 12 weeks, to protect surgeries costing between \$15,000 and \$50,000 seems a no brainer.

CEOFCO: You recently launched the iSmartStep for use with the iPhone and iPod; would you tell us how that will work and what it adds for you?

Mr. Bonmati: I just mentioned how doctors tried to enforce compliance in the hospital, but when the patients are discharged, there is nothing to help them continue the treatment at home. Therefore, the iSmartStep Basic "made for iPod" will help do that. The clinician uploads the treatment to the patient's iPod and the patient takes the therapy to his or her home. In addition, we have developed a SmartStep Secure Server that allows the clinician to monitor directly from his or her office, the patient's compliance at home through Wi-Fi, 3G or 4G.

CEOFCO: You mentioned Japan, China, Europe and the US; as a smaller company, how do you stay focused and get everything accomplished when you have such a wide market, both geographically and for different medical conditions?

Mr. Bonmati: I have done that in the

past in more than 40 countries and it is not difficult with good distributors. Our focus is actually now on the US, because we are actively providing clinical support to MedPro's sales force of about 55 members. This means going in the field and making demonstrations to hospitals and clinics. This is really what is taking our time. Internationally, we defer to excellent distributors that I have used for years before Andante. The distributors handle everything and our contribution is to train them in the use of the SmartStep and its applications. The bulk of the work was to get clinical approval in each country. We got approval in Japan in May of 2011, after 6 months of effort with a distributor I have worked with for 20 years and is now owned by Canon. Now that the approval has been obtained, the distributor does most of the work and we mostly answer questions. Therefore, the international effort is pretty light and it does not unfocus the company.

CEO CFO: Are there any concerns with the new healthcare bill in the US and how it will play into what you are doing?

Mr. Bonmati: The SmartStep will be a plus, no matter what happens with the healthcare reform in the US. Although there is a CPT Code for clinics still paid by the session to reimburse them for the use of the SmartStep (the payback time is between one and three months) the reimbursement trend is towards paying a fixed cost to cover the entire spectrum of the pa-

tient's treatment, from acute care to rehab, down to the home. It is called "bundled payments" and it will be used by Medicare starting in 2013, no matter who wins the election. This is also where the SmartStep is the most valuable for hospitals receiving a fixed amount to rehabilitate a patient and it is already happening. These hospitals can increase their profitability, thanks to the SmartStep's ability to shorten recovery times. Through Tele-Rehab, the SmartStep Server that I mentioned before helps home-care services paid a fixed costs to rehab a patient, increase profitability by reducing or even eliminating the costs of onsite visits. The message to take home here is that the SmartStep reduces costs, which is really what we need to do in healthcare.

CEO CFO: Development is certainly expensive; is Andante Medical Devices funded well enough to get through all of the upcoming steps or will you be looking for additional funding?

Mr. Bonmati: A company is never funded enough. Including the \$3 million that I personally invested in Andante, we have been raising a total of over \$10 million in equity. The company has no debt other than from shareholders advances in between rounds of equity financing. I have raised quality money in units of \$100,000 to \$250,000 from successful entrepreneurs, clinic owners and investment banking executives and I am calling on them for advice and contacts. I will continue to do so for

the \$500,000 we need this year to reach breakeven. We now have 19 individual investors. Once we reach breakeven, we will be ready for funding by institutions or strategic corporate partners. I have already retained an investment banker to raise the \$3 to \$5 million that we will need next year to support our four-year plan. This will include setting up a satellite manufacturing facility in the US to serve the US market that will represent a substantial share of our total sales.

CEO CFO: Why should investors pay attention to Andante Medical Devices today?

Mr. Bonmati: There are four points to take home. (1) Our market is huge and growing, due to an aging population, but also because obesity and diabetes are on the rise. Sports activities and recreational activities are also on the rise, because our aging population wants to live a more active life. In summary, you have a large market that is growing. (2) We are fully in the trend of cost reduction in healthcare, which is a very important point. (3) Andante is fully integrated. It has its own R&D, manufacturing, service, clinical support, sales and marketing. (4) finally, our gross margin is strong at about 80% and we have no bank debt. I think all that makes for a good company to invest into. Personally, I find it exciting to help people achieve a better quality of life, while having a chance to make a significant capital gain. That is what drives us.



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