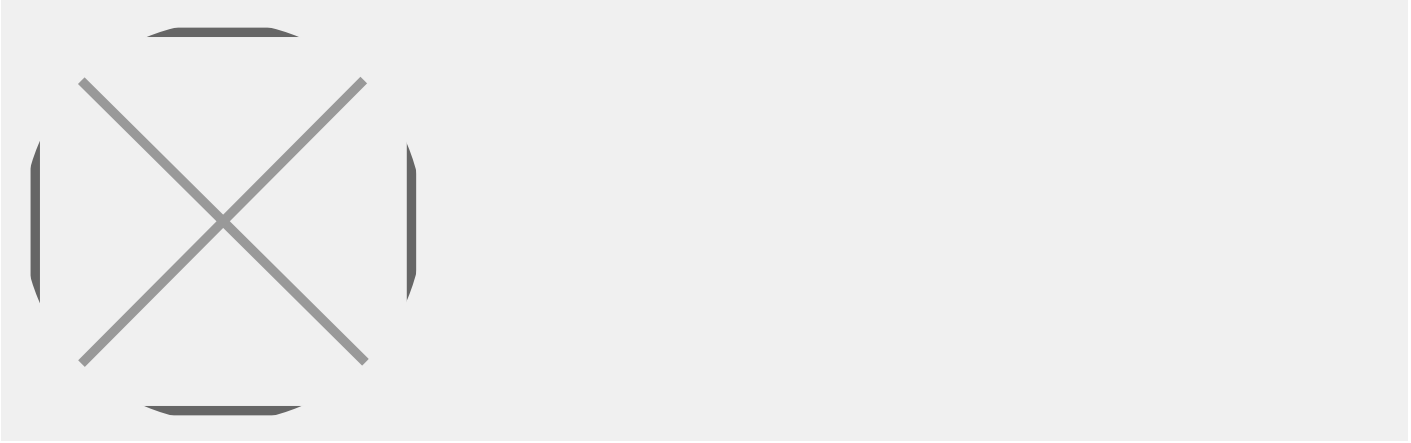
Interview with David Hite, CEO, Alandra Medical México



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Before we get into the company's activities and market, could you give us a brief rundown of your past working experience prior to Alandra Medical?

My experience outside of the United States is extensive, since I had been work-ing for Intel Corp. for more than twenty years and lived in five different countries in Asia and Latin America. In 1999 I started working in Mexico as the Intel Corporation Country Manager and, at that time, the Intel telecommunications chip design group was working with a Mexican chip design company as an outsourcing vendor. The vendor was performing with such good results that Intel decided to acquire the company, and this small 26 employee company grew to become an operation of many hundreds of employees inside Intel today. Further on, we promoted this success story to show that Mexico had a lot of potential with its high level of intellectual capital and excellent infrastructure. Above all, Mexican academic institutions provide very high quality scientists and engineers. I moved on to a series of other international assignments in Latin America and Asia and after leaving Intel six years ago, I came back to live in Mexico. I was not looking for a job in medical devices, but for a Mexican venture capital fund actively investing which was looking for high level executive talent with international experi-ence. What I discovered is this incredible opportunity called Alandra Medical and I was appointed to be the CEO.

It is very important for me to promote Mexican innovation and intellectual capi-tal and that Mexico isn't just manufacturing. Since 2000, the low cost manufactur-ing has been delocalized to Asian countries, and the country has been worried – but that doesn't say much about creating value at a grass root level. It is critically important to provide strength to Mexican small and medium sized organizations that create and innovate. Developed markets can no longer argue that the best

institu-tions and brightest minds are only located in the USA or Europe. Mexico has fantastic world class institutions for generating sci-entific and engineering talent. Besides these institutions, there is a strong commitment in Mexico to science and tech-nology development through CONACYT and the Ministry of the Economy, for example, which fund projects, people and infrastructure to develop these strengths. Mexico also has capital available through its large corporations, although it has to be said that industry could do more in terms of investing in research and development, and particularly in healthcare.

You mentioned the potential of academic institutions and Mexican science in general. What can be done to stop the brain drain phenomenon of professional talents leaving to San Diego for example – and place Mexico on the global map of R&D?

Mexico has within its power the resources to create a culture and business values that richly rewards individuals, small and medium enterprise´s creativity and invention.
California is a place where people can dream of a better quality of life and higher salaries, but also, unfortunately, a high cost of living. These are personal decisions and professional trajectories and little can be done to change that.

Also, some markets, like California, have more investment capital and more entre-preneurial energy available for ideas than others. Mexico has great minds, but scien-tists don’t yet have the robust ecosystem we can find in countries like the USA where a VC will take entrepreneurs out of the idea and prototype stage and fund them to create a product that answers market needs and creates wealth. If I am a Mexican entrepreneur with a great invention or idea, I may choose to go to a country which has a reputation for turning ideas into value.

Therefore, in terms of promoting Mexico as a hub for scientific investigation, the main issue is that most Mexican research is conducted in, and stays within, academ-ic institutions with very little R&D investment coming from large corporations. Alone, these academic institutions do not have the reputation of turning their inno-vations into protected intellectual property and scientific publications don’t create new economic dimensions all by them-selves. Furthermore, they have difficulties bringing their ideas to the market and attracting venture capital funding to create a sustainable economic model. The strong links between investigation to actual intellectual property protection to the generation of value don’t exist. Those links are created by the collaboration of academia, industry and the government and the creation of strong and sustainable capital markets.

To address this, the research paradigm should be shifted. In the case of medical technology you should always start with the identification of a true clinical need identified at the patient bedside. Then, the second step should be to gather scientists and engineers to manifest an innovation, an invention which would be the worthy solution for the identified clinical need. That innovation should both improve or save lives and at the same time generate a new economic dimension that would

attract investment capital and create wealth.

I don’t think the change is imminent, but my deepest belief is that Mexico holds the resources and the opportunity to shift from “Made in Mexico” to “Created in Mexico”. And this is exactly what Alandra Medical is working to do.

Could you give us a brief explanation of Alandra’s business model?

When the Mexican venture fund founded us, they purchased a Mexican medical device company and the assets of a different Mexican medical device company that each had a portfolio of intellectual proper-ty across several different inventions. This merger became Alandra Medical which is now a two and a half year old company. The companies were investigating differ-ent therapeutic areas through scientists, biomedical engineers, industrial and prod-uct designers and clinical research staff working together to generate increased value over their intellectual property, thus enabling eventual successful technology transfers.

Our business model is two-fold. First, we add value to our portfolio of medical device intellectual property. Our objective is to sell or transfer our medical devices to other investors or to medical device com-mercial enterprises.
Our second business model is an outsourcing model to generate revenue and cash flow and become self-sustaining and thereby eliminate investment from private capital. In this line of business we sell en-gineering services to medical device design and development and conduct regu-lated medical device clinical trials in Mexico, mainly for US based medical device companies. Our strengths rely on Mexico´s engineering and clinical expertise, our geographic proximity to the USA, extremely efficient use of capital, ISO certifications assuring our robust quality management system in the development of medical devices and indicator based project management methodology. This allows us to achieve equal or better quality at lower cost than in the United States. Mexico has a robust and professional infrastructure for clinical trials in the country. Also, Mexico’s three major cities are densely populated, with specific institutions dedicated to world-wide relevant therapeutic specialties, ac-cess to tens of thousands of patients, and tens of hundreds of specialized doctors in each therapeutic area. These elements provide us with the conditions to prosper here. The other factor is that the United States are experiencing lower investment from venture capital funds given economic and regulatory uncertainty in the USA and that creates a need for less expensive clinical trials and capital efficient engineering development.

The primary objective of our revenue generating business model is to become an internationally competitive Contract Research Organization (CRO) focused on medical devices with a strong staff, regulatory expertise, expertise in clinical monitoring and access to the most qualified medical doctors and clinical investigators and the best sites at which our clients can conduct clinical research. With the cash flow generated, we can acquire or invest in promising new medical device

technologies – at a great valuation – and accelerate these technologies toward commercial use.

From your proprietary IP portfolio, which main products do you have in the pipeline?

Our company is the majority owner of a technology called the Impedance Spectroscopy Monitor (ISMO). This device is one of the Mexican invented technology portfolios that were acquired at the for-mation of Alandra Medical. This monitor helps a clinician detect when a patient is going into septic shock. We are advanced enough in our prototypes to be conducting animal testing at the Cardiology Institute in Mexico City. We are currently pursuing a regulatory approval for our ISMO monitor in European markets.

Electromagnetic therapy is another inven-tion and is specifically targeted at chronic wound healing for the diabetic foot.

This device is advanced enough to already be in human clinical trials in a clinical site in Monterrey.

We are also actively looking to invest in another medical device project. Perhaps I would like to refer to it as an acceleration project and not an incubation project as we definitely want to advance the value generation and business model of everything we do.

To finance these projects, we are also actively raising new funds.

What are the biggest opportunities that you can spot for the next few years?

Any medical device invention related to identification, early detection or prevention of a disease or illness, or treatment that significantly lowers costs for healthcare providers, is huge in terms of opportunity. The healing of the chronic wound of the diabetic foot is a good example since diabetes is ubiquitous world-wide. There is a lot of great innovation with strong intellectual property available that is not sufficiently funded at the early development stages. We are currently selecting from more than 200 great innovations we have identified for our tech-nology investment acceleration model. We developed a very sophisticated technology evaluation tool that we are validating with our own ISMO and would like to make available to expert bio-design groups of international academic institutions. This tool is part of the value we bring from Alandra Medical.

Do you have a final message about Mexico’s research and potential development and the role played by Alandra Medical?

Alandra Medical’s processes go through a thorough value chain to identify clinical needs, manifest innovation, and create wealth while improving or saving lives. Our focus is to research and develop new innovation defined from clinical needs. We want to be able to accomplish full rota-tions where our engineers would spend time in the ICU, at the patient bed side, and in surgery to observe and gather valuable information to be translated into a valuable medical device invention. I’m urging the organization to choose a huge number of patients as our Alandra Medical goal whom ten years from now have benefited from medical devices innovated by us.

All of that is meant to reflect well on Mexico as a research location, to stimulate other Mexicans to

participate in a value chain, and to be a global testimony of Mexico’s high quality level of research, innovation and creativity.
Alandra Medical intends to be a role model of “Creado en México”.

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