Interview: Nick Duneas – Owner, Altis Biologics, South Africa

06.11.2015

Tags: Pharma, Pharmaceuticals, South Africa, Africa, Innovation, Research and Development, R&D, Funding, Altis, Biologics, Nick Duneas,

The owner of Altis Biologics, Nick Duneas, illustrates the significance of the company's flagship product, the Altis Osteogenic Bone Matrix (OBM) and how the company plans to commercialize the injectable bone graft substitute on a domestic and international scale moving forward. He also highlights how the Innovation Prize for Africa has helped the company achieve an unprecedented level of exposure and credibility, and how this new-found recognition will further enable the startup's growth ambitions.

To begin, Nick, the company was recently awarded the Innovation Prize for Africa for 2014. Can you please highlight the significance of this achievement and how it will support the company's development and market presence moving forward?

For us, it was the crowning achievement following 14 years of research and development of the first regenerating bone graft substitute on the market—the Altis Osteogenic Bone Matrix (OBM). With the help of the Department of Science and Technology (DST), we've trumped all existing technology platforms for non-regenerating injectable bone graft substitutes. As a nation, we're proud to have created the first minimally invasive product that introduces stem cell stimulating growth factors on a scaffold system to regenerate bone defects. It's now become significantly easier, less invasive, less traumatic, and cheaper for patients to undergo operations such as spinal fusions, oral cavity implantations, or bone fracture recoveries. For many decades, the gold

standard has been to harvest bone from the hip. Now, in improving patient outcomes, medical practitioners can obviate hipbone harvesting, which can produce detrimental consequences in terms of both health complications and finances.

The amount of exposure we've received as a result of this competition has been truly tremendous. The USD 100,000 prize money is just a token, and pales in comparison to the value of exposure, prestige, and credibility that we've received—imperative factors for raising additional rounds of funding. In fact, one of our backers, the Technology Innovation Agency was so delighted and impressed with one of their grantees having received this award that they released another round of funding to us. Collectively, we're using these newly acquired funds to build a new laboratory and scale production up ten times, while also obtaining the appropriate FDA and CE marks to eventually access the US and European markets.

Given the widespread prestige of this competition, what type of feedback have you received from the public, private, and academic communities since winning?

As winners of the Innovation Prize for South Arica, we were very proud to place a banner at our booth during the recent South African Orthopedic Conference held in Cape Town. With long queues of industry renowned surgeons from all over the world coming to our table, we received a lot of praise with regards to the sheer level of novelty and innovation associated with the Altis OBM. In fact, a lot of the foreigners were unaware that a company in South Africa had developed a cost-effective bone morphogenetic protein (BMP) complex that had already undergone so many efficacy studies. This BMP-complex is comprised of a multifactorial, synergistic blend of naturally sourced and biocompatible growth factors, so these surgeons were generally quite surprised to see the data, which demonstrated the effective fusion of bone defects in both pre-clinical and clinical studies. The fact that we were the first to market for this technology was a revelation to some of our bigger competitors, who also attend these conferences to evaluate market trends and industry developments.

Currently, we lead the South African market as a BMP supplier for local surgeons. In terms of sales, we are competing against the best technologies offered by the western world by collaborating with smaller budgets and leaner, but high caliber teams. Furthermore, the ability to conduct rapid and high level clinical studies creates a rather unique landscape in South Africa that gives us a competitive advantage when it comes to conducting cost-efficient clinical trials—especially for a small startup like us.

With this new-found spotlight, what type of business development opportunities will the company's commercialization strategies and awareness campaigns specifically focus on from this point onward?

Our main focus now is developing a strong foothold in the local market. We're currently in the process of expanding our infrastructure and establishing a distribution network to quickly gain market share when we commercialize in 2016. Simultaneously, we've been performing many roadshows in the United States to raise awareness for our product and company. At the moment, we have collaborations with two American companies on the West Coast, in addition to a previously established arrangement with one of the largest tissue engineering companies on the East Coast. Our breakthrough came last year when we signed a USD 50 million contract to supply the Brazilian market, further validating our imminent commercial ambitions.

Since 2012, we've had 20 surgeons test out pilot batches of the Altis OBM. In this phase, we also sorted out the product's reimbursement eligibility with appropriate parties—an important process for pharmaceutical companies where the medical insurance companies evaluate their products for reimbursement. This is a critical success factor that we achieved in late 2012. We've taken a less aggressive stance with respect to commercialization—maintaining operations on a relatively small scale with only a few surgeons. Similar to a phase IV clinical study, we wanted to first observe the impact among a smaller population of 500 patients. The results have been promising so far, with surgeons coming back to us time and time again for repeated purchases. Ultimately, to ensure sustainable growth, we're taking small, but solid steps with accelerating momentum as we obtain new levels of added capabilities and infrastructure.

Considering that BMP proteins have been used internationally for many years, how would you evaluate the possibility of similar regenerating injectables entering the market in the near future?

Our competitors have developed recombinant injectable BMP technology, so there are other "me too" products on the market already. However, they're based on recombinant DNA technology, which have had some challenges due to the fact that single component recombinant molecules require high dosages to achieve the same biologic responses as our multicomponent synergistic complex. Unfortunately, there have been some cases with recombinant BMP that have negatively impacted the reputation of the regenerative medicine industry. When used off label in the neck region, the high dose of recombinant factors has led to a small number of unanticipated deaths due to inflammation—causing at least 50 percent loss in US market share and widespread customer apprehension towards our competitors' products. We're now using this opportunity to showcase

that our technology is able to induce bone formation in a much safer and equally effective manner.

To elaborate further, I believe surgeons are switching to our products for two reasons. Firstly, due to the potential therapeutic benefits on South African citizens, the government's avid support has allowed us to price our product at a fifth of our competitors'. The second reason is attributed to safety. Our technology binds the BMP onto an insoluble collagen scaffold—exhibiting a gel-like consistency. The contents of the injection do not migrate away from the injection site and don't cause any tissue changes. In my opinion, this combination of positive attributes has created a distinct competitive and therapeutic advantage—a sentiment that many of our customers are agreeing with.

Considering that bone-related diseases aren't a therapeutic priority among the country's current quadruple burden of diseases, how would you evaluate the demand prospects for this technology in the South African environment?

Indeed, in terms of urgency, bone fractures are not as important as HIV, tuberculosis, or malaria. However, we are a highly industrialized, heavy machinery type of economy with sectors such as mining, in addition to general motor vehicle accidents, causing high trauma rates and, in turn, incapacitation—leaving many with the inability to work. As an example, we recently treated a driver that had experienced a gunshot wound to his hand—leaving him unable to continue with his professional obligations. With the injection of OBM, the driver was able to fully recover and return to work within a relatively short timeframe and at lower costs. So, not only can the OBM positively impact the everyday lives of South African citizens, and in turn the country's employment productivity, but also the ability for people to maintain a certain quality of life after experiencing severe bone fractures. Although not as significant as a cure for HIV or malaria, the OBM has the potential to benefit the 60,000 South African patients that are undergoing bone graft procedures annually.

How would you evaluate the export potential to other countries outside of Africa?

With the US positioned as our primary market in the future, my business partner has just recently emigrated to San Diego, where we are now promoting our technology and trying to partner with an American company to commercialize. More than 800,000 Americans undergo spine fusion every year—further highlighting the pertinence and future market opportunities for this technology. We just completed a pre-pivotal study where we demonstrated that a single injection of OBM containing BMP can fuse the spine within four months. That is one of our breakthrough results of 2014 with regards to spine fusion. We believe that in time, the value and appeal of our technology

will eventually penetrate the three largest and most developed pharmaceutical markets in the world: Europe, Japan, and the US.

Aside from the Altis OBM, what other R&D projects does the company currently have in its pipeline to diversify its portfolio?

We refresh our generation of biotech products every 10 to 15 years. We're now trying to recreate this natural BMP complex, which contains numerous synergistic bone morphogens using recombinant DNA technology, but with much smaller quantities to achieve the same biologic effect. We've already published a paper in 2013 to show that we can extract components of the complex from nature and reconstitute it to show synergy. Therefore, we believe that synthesis of recombinant molecules and proteins can be reassembled into one complex to achieve a fully synthetically manufactured product. This is significant because there are challenges using animal derivatives. For example, we're currently using a porcine derivative, which leaves us unable to access Islamic markets; in this case, we'd have to use bovine or a recombinant protein to comply with religious standards. The next generation of products will place more of an emphasis on delivery systems—the scaffold upon which the biological system can infiltrate with its stem cells. So, the architecture and geometry of the scaffold system has to be engineered better, as well as the binding of the new recombinant complex. Essentially our next phase of research and development will focus on creating even better tissue engineering technology for bone regeneration in the next ten years.

As the founder of this startup, what is the one piece of advice you would give other aspiring entrepreneurs on building a company in a sustainable, but fruitful manner?

The most crucial asset that an entrepreneur can have is innovative technology coupled with the proper patent protection. The most fundamental component of a tech entrepreneur's journey is acquiring intellectual property (IP), in terms of product innovation and technical capabilities, but more importantly industry insight and expertise. The biggest challenge lies in translating an intangible asset into a tangible proof of concept, especially with respect to fundraising. Speaking from personal experience, I found that our lack of credibility among the global biotech community significantly limited our access to private investors—leaving the government as the only source of funding available. With limited resources, startup owners must exude a degree of flexibility and adapt their strategies accordingly—perhaps first entering markets or business segments that do not directly align with the core strategy. I spent seven years in a non-profit human tissue bank, solely to leverage its technology platform and establish credibility. We eventually licensed two patents to the tissue banking industry, which are still in effect today, now having helped treat

roughly 40,000 patients. Beyond the royalties, which have invariably helped support the development of Altis Biologics, the added degree of credibility is what really helped us pivot to a steadfast growth trajectory.

In terms of reputation, capabilities, and performance, where would you like to have positioned the company in the next three to five years?

As Altis Biologics, we want to become a respected company and grow our market share, while establishing a firm foothold in the local environment to more effectively fulfill the clinical needs of South African citizens. Also, we want to have completed pivotal clinical studies on a large scale and obtain the appropriate regulatory approvals within the next few years. In addition to other metrics, we will be measuring our success by the number of patients we treat, and ultimately, the type of impact we'll have on improving patient outcomes. Personally, this is my primary driving factor. The implications of this technology are simply fascinating, and I'm looking forward to seeing it succeed.

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