Interview: Jonas Wang, Ph.D. â?? Chairman & CEO, StemCyte, Taiwan

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Jonas Wang Ph.D., Chairman and CEO of StemCyte, a global leader in Regenerative Therapy field including cell processing and transplantation located in the US, Taiwan, and India, provides us with an overview of the impressive phase II results recently received by its breakthrough regenerative therapy for spinal cord injury. While it now looks at leveraging its unique, in-house developed technology platform to target other neurological disorders such as spinal cord injury and chronic stroke, the company also plans to IPO in Taiwan before the end of 2017.

Founded in 1997, StemCyte has been growing through a hybrid structure gathering public and private cell banking to become a global leader in cell processing and transplantation. You became COO of the company in 2009 and its CEO in 2011. How would you describe the strategy driving the development of this innovative company?

We are actually employing a â??Dual Tractâ?• strategy with two key pillars: first, the strengthening of our core business, which encompasses a hybrid model of offering public and private cell bank services; second, the clinical development of innovative regenerative therapies. StemCyte established its public bank offering in 2000 and its private counterpart in 2005, which is now profitable. The latter hence provides us with the revenue stream we need to nurture the advancement of our R&D projects, which are leveraging umbilical cord blood stem cells to treat neurological disorders such as spinal cord injury and chronic strokes. For the clinical development of these projects, we notably collaborate with some of the most prestigious research centers and academic institutions in neurosciences, both in Taiwan and the US.

In 2000, StemCyte became fully operational with public banking facilities in the USA and Taiwan, before launching the private banking division in Taiwan and in the US in 2005, followed by your entry into the Indian market in 2010. How does StemCyteâ??s hybrid model stand as a competitive advantage for the company?

Only five years after we set up our public bank activities, StemCyte successfully supplied more than 500 transplant units to over 300 transplant centers around the world. Based on this early success, our medical advisors stressed to our companyâ??s board the great opportunity we held to bolster StemCyteâ??s revenues by setting up a private bank branch in parallel to our public cell bank offering.

Private customers are particularly eager to put their babiesâ?? cord blood in the best hands and see it stored in the most stable and secure environment possible, in order to ensure cord blood units will deliver their full therapeutic potential when needed, even if that is in a few decades. Nevertheless, the large majority of private cell banks do not display the same technology level as public cell banks, for the simple reason that public cell banks are required to comply with more stringent regulations and scientific expectations.

Through our hybrid model, we offer our private customers a level of technological expertise and regulatory compliance which is usually only accessible through public cell banking. This hybrid approach truly stands as our companyâ??s most valuable competitive advantage and it will always remain at the core of our growth strategy, although more than 85 percent of our revenues already come from private banking activities. StemCyte now proudly stands out as one of the largest cell companies in the world displaying such a hybrid model, and the opening of our new storage facility in Baldwin Park (California), which objectively stands as one of the most high-tech facilities of its kind, will help us to propel the further development of both our private/public cell banks and Regenerative therapy.

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Although the global stem cell banking market is expected to reach USD 3.96 billion and grow at a CAGR of 20.2 percent from 2016 to 2021, it also stands as an extremely competitive market, especially in the US. To what extent has this hybrid approach allowed Stemcyte to generate growth in 2016, and what is the outlook for 2017?

The US indeed stands as a particularly competitive market for private cell banking, as there are already more than 30 companies active in the country. Since most of our competitors are only active in the private bank market, where regulations are less constraining, they do not have to spend the money to meet the quality requirements of public banks. This allows our competitors to offer a product that is cheaper. But, our focus is on higher quality and meeting the stringent regulations required of a public bank. With our hybrid model, though we are on the higher end of the competitive landscape, we provide our private customers the elevated quality of a public bank. This has resulted in StemCyte having the highest cord blood transplantation success rate. As a matter of fact, StemCyte is the only cell bank with private activities that boasts a track record of more than 2,000 units shipped for transplants. As a comparison, StemCyte has supplied much more UCB units for transplants than the total combined number from all the other ~30 private cord blood banks in US.

In 2016, our global revenues amounted to over USD 20 million and we hold great expectations for 2017, as we will be able to leverage the potential of our brand-new storage facility. All our clients who visited this cutting-edge GMP facility were unanimous: this is where they want to store their babiesâ?? cord blood!

Looking at the geographical breakdown of our revenues between India, Taiwan and the US, the American market still makes up more than 80 percent of our revenues. In Taiwan, our companyâ??s other historical market, the growth of our revenue has been slightly hindered by the countryâ??s low birth rate, while India will indisputably stand as a strategic country for the long-term growth of the company, with 126 million babies born in 2016.

All of our three storage facilities have been awarded the most prestigious quality and safety certifications. For example, in 2016, all three StemCyte facilities were re-accredited by FACT (Foundation for the Accreditation of Cellular Therapy) for both its public and private banks. We are very proud to be one of only five companies offering private cell banking to hold FACT accreditation in the US, while our Indian and Taiwanese facilities also received this reputed certification.

In the meantime, how are you advancing in the clinical development of regenerative therapies?

Our first and most advanced R&D project aims to treat patients suffering from spinal cord injury (SCI). We have developed a patented process to extract mononuclear cells from cord blood units, as well as a patented storage technology and a unique transportation system to ship these cells all around the world. Thanks to this in-house technology platform, mononuclear cells can be used up to five days after their extraction, during which we can guarantee a similar level of therapeutic efficacy as with traditional transplantation methodologies. This stands as a real breakthrough; previously, transplants had to be used within 24 hours.

We just released positive results for a phase II clinical trial conducted in China, which aimed to prove the efficacy of our technology platform. For this trial, we did the cell extraction in the US, before shipping the mononuclear cells to China, which takes three days overall. The cell injection was then done in China, four days after the extraction. This trial involved twenty SCI patients who were wheelchair-bound for an average of 7 years. After a single injection of our mononuclear cells, these volunteers underwent intensive rehab â?? mostly composed of walking exercise: six hours a day, six days a week, for six months.

SCI patients can suffer five life-altering symptoms: immobility/paralysis, urinary incontinence, bowel incontinence, impaired sexual function, and neuropathic pain. Forty-eight weeks after treatment with our mononuclear cells, 15 patients (75 percent of the sample) can now walk. 60 percent of them can defecate and urinate by themselves while 100 percent of these patients do not feel any neuropathic pain. Although we did not collect scientific data related to the improvement of their sex lives, some of these patients now have babies.

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These results, which were published in a scientific journal, are among the most impressive in the history of SCI treatments. We are now about to conduct another phase II clinical trial in the US, which we expect to start in June 2017. In the same vein, we will also conduct similar phase II clinical trials in Taiwan and in India, which should start before the end of 2017. Initially, StemCyteâ??s technology platform was developed by Rutgers Universityâ??s Dr. Wise Young, one of the most reputed neurosurgeons in the world. As our companyâ??s Chief Science and Medical Advisor, he designed and supervised the clinical development of this unique technology platform. Given his unique expertise, I am particularly optimistic about the positive development of this unique technology platform.

What is the second R&D project you mentioned?

In the meantime, we plan to start the clinical development of our second R&D project in 2017, for which we want to leverage the same technology platform to treat patients affected by chronic strokes. We want to conduct the phase I clinical trial in Taiwan, the perfect country to conduct high-quality, cost effective clinical trials, where we will be able to easily access a large patient population. Again, I am confident this trial will be perfectly handled, as it will be directly supervised by StemCyte Taiwanâ??s Chief Medical Officer, Dr. John Lin, a Taiwanese Professor of Neurosurgery specialized in chronic stroke and Superintendent, Hualien Tzu Chi Hospital.

The stroke market is ten times larger than for SCI therapies, which means that over 30 million patients around the world could benefit from this kind of regenerative therapy. Despite the huge market potential that these two products hold, our company is highly committed to make these treatments as affordable as possible.

How do you plan to finance the clinical development of these products?

In the grand scheme of things, our vision is to leverage our technology platform and mononuclear cells to develop similar treatments for other neurological disorders, including Parkinsonâ??s and Alzheimerâ??s diseases. Nevertheless, our first and foremost priority is to favor a step by step development approach and concentrate our efforts on advancing our SCI treatment, whose great clinical results will undoubtedly draw the attention of potential partners over the upcoming months.

Our companyâ??s board, including our two main investors Fubon VC fund, Taiwanâ??s largest financial institution, and Diamond BioFund, Taiwanâ??s largest biotech-focused fund, chose the Taipei Stock Exchange (TSE) for the upcoming IPO of the company. With the resources it will generate, we want to nurture the mid-term growth of the company, progress in the clinical trials of our SCI and stroke treatments and also enter the Parkinsonâ??s area. In terms of timelines, we expect to complete the first step of the overall IPO process *(the listing on Taipeiâ??s Emerging market, ed)* before the end of 2017.

Thanks to our pre-IPO round of financing, we currently hold the financial means to move our SCI treatment forward by ourselves â?? at least to a certain extent. We are however also looking for partners that will support us in the completion of its clinical development. As former Vice President of Research and Technology of Johnson & Johnson, I would prefer to partner with a Big Pharma or a large biotech company. When I was at J&J, I piloted the acquisition of two large companies, Neutrogena$^{Â®}$ and RoC$^{Â®}$ Skincare, which were designed to find market exits for patents I invented. My experience working at a leading American healthcare company has honed my expertise in international partnerships and acquisitions that I can now leverage to the benefit of StemCyte. Although it will be subject to negotiations, we plan to develop a global partnership for the development of this extremely promising product.

What is your vision for the mid-term development of the company?

StemCyte can become a global leader in regenerative therapies, bringing life-changing solutions to SCI and stroke patients first, before moving to other neurological areas. In the meantime, we will not forget to generate value for our shareholders. Currently, StemCyteâ??s market capitalization is around the USD 200 million mark. If we manage to develop our aforementioned treatments for SCI and strokes, we can easily become a billion dollar company. As a public cell bank, we hold direct access to thousands of cord blood units, which are the raw materials for these regenerative treatments. This stands as a great competitive advantage, which should further accelerate the growth of the company.

During your career with J&J, you developed more than 10 core technologies and filed more than 30 business-related patents, while holding prestigious positions among the corporate

structure of the American healthcare giant. What excites you the most about this new challenge at the helm of StemCyte ?

> â??With more than 2,000 transplants units successfully delivered to transplant centers around the world, StemCyte is already saving lives on a daily basisâ?•

At J&J, I strove to invent the best anti-wrinkle technologies and products, which indisputably contributed to making millions of women feel more beautiful and confident. Nevertheless, as the holder of a PhD in pharmacy, my personal goal has always been to save lives.

With more than 2,000 transplants units successfully delivered to transplant centers around the world, StemCyte is already saving lives on a daily basis. Nevertheless, this is not enough to me. Considering the game-changing technologies we are developing and the incredible people we have on our teams, we can bring greater outcomes to a larger number of patients. As Chairman and CEO of StemCyte, I want our company to save more lives, which will imply becoming the most innovative stem cell company in the world and a global frontrunner in regenerative therapies.

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