Interview: Howard Lee PhD – Chairman & CEO, Easywell Biomedicals, Taiwan



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Howard Lee, chairman and CEO of Easywell Biomedicals, documents the most exciting R&D projects that will drive the company to new heights; spanning from a life-changing Parkinson's transdermal patch to a ground-breaking regenerative therapy in advanced wound care. Easywell was recently ranked the tenth fastest-growing high-tech company in Taiwan by Deloitte's "Fast 500 Technology APAC," displaying an impressive 367 percent growth rate in 2016.

You have been responsible for Life Sciences Investment at the CID Group, one of the fastest growing Asia-headquartered private equity firms focused on top emerging Greater China companies, since 2010. How did you become chairman of Easywell Biomedicals?

The CID Group manages five LP Funds for over USD 1.5-billion capital. Our Fund III, for example, amounts to USD 400 million, with a portfolio of 40 companies, way above the industry average of 20 companies per portfolio. With more than 90 collaborators, the CID group already stands as one of the largest private equity firms in the region. Nevertheless, managing a fund of USD 400 million still represents a challenging task for a structure of our size, especially when its portfolio gathers 40 different companies.

As a result, when – in 2013 – our Fund IV received a commitment of USD 400 million, our limited size left us with no choice but to ultimately decide to manage a capital of only USD 100 million for

this fund, including USD 50 million of CID’s own capital.

Around one and a half years later, after we completed our Fund IV investment, we again decided to only manage a capital of USD 150 million for our fund V – half of it being CID’s money as well.

Owning 50 percent of the capital of these Funds IV and V, we hence could evaluate a broader set of investment options than usual and our analysis of Taiwan’s stock markets at this time led us to consider the acquisition of a publicly listed company. This decision marked a real shift in CID Group’s investment policy, as we moved from a traditional VC fund approach to a buy-out fund strategy, where investors aim to turnaround the companies that they are taking over.

Leveraging the USD 100-million capital of our Fund IV, at the end of 2013 we acquired a Taiwan-based healthcare company, Actherm Inc, which was facing tremendous economic difficulties. Focused on the development and sales of thermometers manufactured in plants located in Shenzhen and Dongguan (China), the company was hit by increasing labor costs in this country and the sharpening competition in key international markets, such as Germany, while the unfavorable currency context was further worsening its financial situation. As the new majority shareholder of the company, we decided to change the company’s focus. Moving from the medical device field where it was facing price-oriented competition, Easywell rapidly evolved under our impulsion to reach a market positioning generating more value in the long term.

What have been the main milestones leading to the transformation of Actherm, a company in financial difficulty focused on the development and manufacturing of thermometers, into Easywell Biomedicals, a company active in the pharma, regenerative medicine, and medtech sectors?

In 2014, Actherm became a fully integrated biopharmaceutical company after we acquired over 90 percent of the capital of the US-based company Magnifica, which holds a well-established API-trading business worth around USD10 million annually. In parallel to its trading activities, Magnifica was developing three treatments eligible to a US FDA 505(b)(2) filling, but we identified its R&D team was not substantial enough to develop these products within satisfactory timelines.

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We then acquired a good team with strong formulation capability led by Dr. Yu-Hsing Tu, and decided to self-establish a cGMP pharma development and manufacturing facility located in New Jersey, close to the US FDA’s offices. We also formed a new company, TULEX, in which Eayswell now owns 90.2 percent of the capital.

We now hold a team of more than 40 scientists based in New Jersey and working on new formulations and dosages, essentially Rx-to-OTC drugs *(which refers to the transfer of proven prescription drugs (Rx) to nonprescription medicines OTC status, e.d.),* which we identified as a great market niche for a company of our size. While Big Pharma companies are now essentially focused on the hospital sector, most of the US giants of the retail sector such as Wal-Mart and Costco rely on private labels for the development and manufacturing of their OTC products. Providing these retailers and their huge sales networks with new, US FDA-approved, OTC products could indeed entail extremely interesting growth opportunities for our company, and this is precisely the strategy we are currently following.

Easywell's R&D pipeline is focused on two main areas: high-barrier, Rx-to-OTC generics and 505 (b)(2)-eligible drugs. How are you advancing in the development of your pipeline of high-barrier generics?

First, I would like to highlight one of the main specificities of our overall R&D strategy: while some Taiwan-based companies rely on in-licensed products for which they only own local rights, Easywell holds the global rights of all our products under development. This makes a crucial difference when it comes to estimating our expected return-on-investments.

As part of our high-barrier generics R&D pipeline, we currently hold six different treatments in development. So far, we have already submitted one P4 Abbreviated New Drug Application (ANDA) for TLX-001, an extended release respiratory cold medicine, with a market entry expected for September 2017. We have also submitted a P3 ANDA for TLX-006, a treatment for breast cancer, while we will submit a P3 ANDA for TLX-005, a new formulation for a urinary medicine, in early 2017.

When selling the commercial rights of our products, we usually negotiate a 30 percent royalty fee. One of the commercial agreements we have already closed overcame the USD1-million mark, and we expect to fill four more ANDA submissions before the end of 2017. In this regard, we are currently discussing with two potential partners, and the upcoming deals should again overcome the USD1-million mark.

Another specificity of Easywell indisputably lies in its unique manufacturing capacity, as it is one of the few Taiwan-based companies holding a cGMP plant in the US. Although we can handle the manufacturing of all products for which we have already submitted an ANDA, we however want to further expand this manufacturing facility in 2017.

Looking at your pipeline of products eligible to a 505(b)(2) pathway, Easywell is developing a life-changing transdermal Parkinson patch. When do you expect to bring this game-changing product on the market?

This transdermal patch will indeed be extremely useful to Parkinson's patients, who usually struggle to take oral pills. We already started a Pivotal PK Clinical Trial in Malaysia, where clinical trials' results are recognized by the US FDA. This Single Ascending Dose (SAD) trial gathers twelve volunteers and aims to prove the efficacy of our transdermal patch, which we developed from an existing oral dosage. Week after week, we are monitoring drug concentration in patients' blood to ensure it is strictly similar to the concentration obtained with the original oral form. Once we get the final results of this trial, we will submit these data to the US FDA, which may ask us to conduct a multiple ascending dose (MAD) PK pivotal study before eventually granting market approval to product.

Regulations for 505(b)(2) products are slightly different than for innovators and generics products, and they can vary a lot from a country to another. As a result, we are looking for different partners for each market we consider to enter, and we want to close these commercial partnerships before receiving our final regulatory authorizations. As 505(b)(2) products lay somewhere in-between new drugs and generics in terms of marketing strategy, we are looking for potential partners holding strong connections among the hospital sector as well as in the physician and specialist communities of our target countries.

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The market potential for this treatment is absolutely mind-blowing: the global sales of the current oral treatment already amount to over USD 600 million. By bringing a transdermal patch to the market, we expect to both ease treatment usage and increase patient adherence, meaning that market size should increase too. In other product categories, we already saw that the market entry of transdermal treatment form increased market size up to fivefold. In the past, most of the patches brought to the market were also more highly priced than oral dosages – usually around twice the price of the pill – as soon as the heightened efficacy and therapeutic advantages of the patches are clearly proven.

With the acquisition of Transwell Biotech in 2016, Easywell gained access to a new business sector: regenerative medicines. What rationales motivated you to expand the scope of the company's activities?

Transwell Biotech is an early stage company focused on regenerative medicines, which was part of CID Group's Fund IV. Only two years after we invested in this promising company, Transwell had already reached eye-catching milestones in terms of product development, which prompted us to move forward on our initial plan to merge Transwell and Easywell.

Through Transwell's acquisition, Easywell can now access various technology platforms such as a DMSO-free cryopreservation media and cell delivery systems, a warehousing facility holding 10,000 gown-in/gown-out cleanrooms equipped with heating, ventilation and air conditioning systems as well as analytical, product and process development units.

More importantly, Transwell holds an exclusive in-license partnership with Elanix, a spin-off company from the University of Lausanne (Switzerland), for the supply of 2cm² fetal skin cells. By leveraging Transwell's cell expansion technology, we can then build from a single fetal skin sample a complete cell carrier, which can be used as an advanced wound care product. This product, TWB-103, is about to start its clinical development in Taiwan, Japan, and in the US, where the US FDA and Taiwan TFDA already approved our IND. As a result, we plan to start a phase I/II global trial in 2017, while in Japan we are still waiting to receive our IND.

Japan stands out as a particularly strategic market for this product, especially since Japan's PMDA released in November 2014 updated regulations granting conditional approval to products displaying reasonable safety and efficacy results for their phase I trials. As a result, we expect Japan to be the first market to receive this product, potentially before the end of 2017, if we however manage to find the right local commercial partner by then.

What will set your regenerative wound care product apart from the competition?

Looking at the competitive landscape, TWB-103 will only face a very limited number of competitors on the global stage, while most of these competitors' products are based on neonatal cells. Our own technology being based on fetal cells, we then expect our product to stand out from the competition by displaying no host immune rejection, a faster healing process, and a lower cost, as TWB-103's technology is not based on expensive collagen carriers like most of our competitors.

These competitive advantages are particularly exciting when considering the advanced wound care market is set to grow at a CAGR of seven percent from 2015 to 2020 to reach USD14.9 billion (according to a study of MarketsandMarkets released in May 2016).

What kind of synergies could you further enhance between the different business units of Easywell?

First, our OTC and medtech products target the same main retailers, namely Wal-Mart, Costco, and CVS for the US market. Ideally, our objective for the midterm would be to offer them a more holistic care approach, by complementing the therapeutic outcomes of our high barrier generics with companion diagnostics from our medtech branch, such as associating our fever treatments with our thermometers.

Although building synergies between our different business units is absolutely paramount, we also want to become more focused on our core competences: drug development and manufacturing. In this regard, we are currently looking for a cost-effective partner to handle the manufacturing of our medtech products, as the profitability of our Chinese plants remains largely unsatisfactory.

As Chairman of the company, what is your vision for the development of Easywell Biomedicals?

I want Easywell to become an integrated healthcare company that holds a strong, in-house R&D capability, which will allow our company to always hold the global rights of all the products we want to develop.

By fully leveraging our proprietary technology platforms, 505(b)(2) products should bring great growth prospects to the company, as many crucial treatments are still only available through injectable and/or oral dosage forms around the world. By holding the global rights of promising 505 (b)(2) products, bringing to the market our innovative regenerative therapy for advanced wound care, and further enhancing synergies between our different business units, Easywell displays a very limited risk exposure while targeting huge market niches which should deliver very promising growth rates for the upcoming years.

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