

# Company Update

## July 2008

### Key Points

- **ReCell® concept & kit gains SFDA approval**
- **Lucrative Collatamp® G product licensing agreement signed**
- **Shareholder Briefing Functions**
- **China's Pharmaceutical Market: An overview**
- **SFDA Regulatory Delays**
- **Stakeholder Relations Manager appointed**
- **Swiss based Business Development Manager appointed**

The Old Swan Brewery  
Level 1, 173 Mounts Bay Rd  
Perth WA 6000

Phone: +61(0)8 9321 4606  
info@helicongroup.com.au  
www.helicongroup.com.au

### Chinese SFDA approves ReCell® concept and kit

We are pleased to announce that earlier this month the Chinese State Food and Drug Administration (SFDA) granted approval for the skin regeneration concept and device, ReCell®, for sale in China.

The approval process for the product has been complicated and intensive due in part



to the pioneering nature and complexity of the ReCell® kit. Importation issues with some components of the kit are being resolved with the SFDA.

The technology utilises a patient's own skin cells thereby achieving improved matching of the skin's texture and colour in the treatment area and eliminating the likelihood of tissue rejection.

Our CEO Peter Abrahamson said, "We are pleased that we have achieved this milestone in China's challenging regulatory environment and we are now exploring all avenues to resolve the importation issues including local sourcing to enable commercialisation to commence."

ReCell® was developed by Professor Fiona Wood who successfully used the treatment approach on, amongst many others, victims of the 2002 Bali bombings.

The product is part of Avita Medical's (formerly Clinical Cell Culture) portfolio of tissue engineering medical devices and has proved highly effective in the treatment of burns, small wounds, encouraging scar free healing and re-pigmentation.

The target market for ReCell® includes plastic reconstruction surgeons, dermatologists, burn specialists and cosmetic specialists in military and high end hospitals, as well as larger private hospitals in the major metropolitan centres of China.

The technology has huge sales potential in China where the cosmetics and plastics markets are growing exponentially, due to an emerging middle class with disposable income.

Estimates put the amount spent in this market annually in the order of US\$2.4 billion and there are more than 3,000 cosmetic surgery units in major hospitals in China.

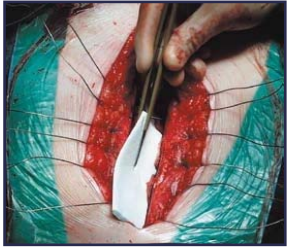


Neck scar as a result of burn



Neck scar 12 months after treatment with ReCell®

## Lucrative product licensing agreement signed with EUSA Pharma



In May we signed an exclusive product licensing agreement with EUSA Pharma for Collatamp® G for the Chinese market.

The collagen based device is an implantable sponge that contains the widely effective antibiotic, gentamicin.

It has a CE Mark for sale in the European market.

In controlled clinical trials Collatamp® G has been shown to significantly reduce the incidence of severe post surgical infections whilst lessening the risk of toxicity and the associated side effects of systemic Gentamycin. This in turn leads to faster recuperation.

The sponge remains inside the body post surgery whilst, over a period of 7-10 days, the collagen is safely absorbed by the body releasing the antibiotic at the site of potential infection.

The benefits of this technology are that the high concentration of antibiotic released at the surgical site minimises the chances of infection and leads to faster recuperation without the negative side effects of the antibiotic.

The product also functions as an exterior wound dressing and has been shown to, for example, control severe infections in diabetic foot ulcers thereby significantly reducing the likelihood of amputation.

It can be utilised across a wide range of surgeries including orthopedics, bone infection, cardiac surgery and vascular surgery.

The deal with EUSA Pharma, a highly innovative specialty pharmaceutical company focusing primarily in Europe and the USA, also provides us with first right of refusal for new products that the company develops or acquires.

On signing the agreement, our CEO Peter Abrahamson said, "Apart from adding another innovative technology to our portfolio, the alliance with EUSA Pharma is strategically a very important one for Helicon, potentially adding a stream of exciting new products to our portfolio in the years to come."

We are currently preparing the product dossier for submission to the State Food and Drug Administration (SFDA).



## Shareholder Briefing Functions

Over the course of the last couple of months we hosted a series of shareholder briefings that incorporated presentations given by our Shanghai based CEO Peter Abrahamson and our Chairman Saliba Sassine. These were followed by Question and Answer sessions, as well as opportunities for shareholders to meet with members of the Board and Management one on one.

The briefings updated shareholders on company developments, which included a review of our strategy, the recent addition of Collatamp® G to our product portfolio, as well as our plans for the next two years.

During the Q & A sessions some of the key shareholder concerns raised revolved around the delays in the regulatory approvals in China. Shareholders were informed that the ongoing restructuring within the Chinese State Food and Drug Administration as it upgrades systems and approach to world best practice was the primary reason for the delays.

Overall the events reinforced to shareholders that our company strategy is on track and that our future looks promising.

Further briefings are planned for when Peter is next in Australia in August 2008.

Attendees expressed an appreciation for Helicon's initiative to provide shareholders with the opportunity to hear firsthand an update on our company's development.



Perth Shareholder Function: May 2008

## China's Pharmaceutical Market: An Overview

China's pharmaceutical market is growing at an incredible rate and is showing no signs of slowing down. Fuelled by a rapidly developing economy, changing cultural needs and trends as well as the government's commitment, outlined in the nation's 11<sup>th</sup> Five Year Plan, to making biopharmaceuticals one of China's leading industries within 15 years<sup>1</sup>, the nation's pharmaceutical market looks set to become one of the biggest world-wide.

International analysts believe that China will become the world's largest pharmaceuticals market by 2050. Some experts also predict that the Chinese drugs market will grow at an annual rate of 20 to 25 percent in the next five years<sup>2</sup>.

The total value of the market was US\$12.8 billion in 2005<sup>3</sup>. Currently chemical and biotechnology products make up 70 percent of the market, with traditional Chinese medicines (TCM) making up the remaining 30 percent. The market is split between products from domestic producers or Chinese joint ventures and imported medicines that are registered through the SFDA of China<sup>4</sup>.

With a population of over 1.3 billion, China is the world's most populous country and it continues to grow at an annual projected rate of three percent<sup>5</sup>. This huge market size, coupled with an ageing population that consumes more pharmaceuticals than its younger counterparts, makes China an attractive market entry prospect for pharmaceutical companies.

Another demographic trend that is aiding the growth of China's pharmaceutical market is higher living standards which result in consumers having more disposable income to spend on healthcare<sup>6</sup>. Also the growing urbanisation trend in China creates lifestyles that are more conducive to pharmaceutical use and provides consumers with greater access to drugs through retail pharmacies<sup>7</sup>. China now has 166 cities with at least one million inhabitants as compared to the USA which has nine such cities<sup>8</sup>.

Put succinctly, China is gaining a great deal of attention from foreign companies due to its healthy economy, increasing rates of disease diagnosis, increasing rates of treatment, cost advantages, growing well educated workforce and enormous long term market potential<sup>9</sup>.

China's accession into the World Trade Organisation (WTO) in December 2001 has also added to its attractiveness to foreign entities. The Trade –Related Aspects of Intellectual Property Rights (TRIPS) Accord which mandates that drugs receive at least 20 years of patent protection officially came into force in China at the end of 2002<sup>10</sup>.

TRIPS is going some way in enforcing a greater level of IP protection and thus minimising some of the risks involved with foreign investor entry into the Chinese market.

China's entry into the WTO has also created a greater level of policy transparency and overall more development opportunities for foreign investors. Ultimately, whether a foreign enterprise can turn the market potential into reality depends on its research, development and marketing, as well as its adaptation to the situation on the ground in China<sup>11</sup>.



We have identified the huge growth potential in China's pharmaceutical market as a viable business opportunity, which, when managed effectively, will reap the rewards for our company and its stakeholders. Our unique business model which focuses on minimising risk and maximising shareholder return, our experienced board and our comprehensive product selection criteria all serve to amplify our success rates.

## SFDA Delays Regulatory Approval of New Products

The last twelve months have seen a significant slowdown in the State Food and Drug Administration (SFDA) product approval rate, with only 70 import licenses for new pharmaceuticals being granted in 2007, compared to 125 in 2005. The SFDA is the Statutory Body responsible for the evaluation and approval of applications to license pharmaceutical and medical devices for sale in China.

An article in May 2008's *China Pharmaceuticals and Health Technologies Weekly* outlined the reasons behind the delays in the drug approval process, as described by an industry insider.

The reasons included were:  
*"That almost 60 percent of the human resources in the SFDA's Center for Drug Evaluation (CDE) are devoted to reviewing clinical trial applications for generic drugs and the CDE is required to complete reviews of generic drugs, which are subject to shorter clinical trials, within a shorter time frame than novel drug reviews. Hence multinationals are finding that their drug trials are being put on the back burner.*

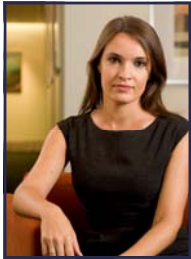
*Added to this, an under staffing problem is also contributing to the length of time it takes to complete clinical trial reviews<sup>12</sup>."*

To further compound the problem the SFDA is raising the bar for novel drug registration. For example, the SFDA recently announced that they would only allow drug companies' one opportunity to file their application documents; if a company's initial application does not satisfactorily prove the safety and efficacy of its product, the SFDA will no longer request further information, but will reject the application outright<sup>13</sup>.

Our company is just one of many whose plans have been affected by these issues over the last two years.



## Stakeholder Relations Manager Appointed



As our Stakeholder Relations Manager Aleksandra Gajda's role revolves around ensuring that our company's stakeholders are kept up to date with ongoing developments as it implements its ambitious growth plans. She is responsible for creating and implementing company communication strategies that effectively target stakeholders and maximise support for our company.

Aleksandra holds a Bachelor of Mass Communication (Major in Public Relations, Marketing and Journalism) from Curtin University of Technology in Perth.

Her appointment is part of a strategic initiative that recognises our need to keep stakeholders aware of company advancements.

She said the opportunity to work at Helicon enables her to contribute to the company's development as it enters a period of swift change.

"I am very excited to be part of such a new and rapidly expanding company; there are many plans in the pipeline for Helicon and I am enjoying the challenge of being involved in this growth opportunity," said Aleksandra.

Commenting on her appointment, our CEO Peter Abrahamson said: "We are committed to maintaining regular communications with our stakeholders and Aleksandra's role is solely focused on honouring that commitment."

## Business development activities heightened



Our Business Development Manager, Swiss based Anita Wehrli focuses on identifying and liaising with potential product partners during negotiations for the exclusive rights for the Chinese and other North Asian markets.

Anita has held a number of key business development and client relations roles within the healthcare, mining and agricultural sectors, most recently as BDM of

Visiomed.

She completed a Bachelor of International Business (Major in Marketing and Management) and a Master of Business Administration (Major in International Business- China), both from Murdoch University in Western Australia.

Anita's appointment aids us in our plans to build our organisation's product range within its portfolio areas. The position is based in Europe because this is the locus of many of the small to medium sized research focused medical and pharma companies whose products are licensing targets for our group.

Our CEO Peter Abrahamson said: "A critically important part of our growth strategy is to add innovative products to our portfolio and Anita brings invaluable experience and drive to enable us to achieve this objective."

Commenting on her appointment she stated: "Given Helicon's growing network in North Asia I am focused on assisting the company in locating products that can be introduced successfully into the region's biomedical markets, especially China."

## References

1. Fu J 2008, 'Biotech sector shows bright future', *Shanghai Daily*, viewed 15 April 2008, [www.shanghaidaily.com/emagazine](http://www.shanghaidaily.com/emagazine)
2. Yuanjia H, Geng F, Ying B & Yitao W 2007, 'The Chinese pharmaceutical market: Perspectives of the health consumer', *Journal of Medical Marketing*, 7, viewed 15 February 2008, [www.palgrave-journals.com/jmm/journal/v7/n4/abs/5050099a.html](http://www.palgrave-journals.com/jmm/journal/v7/n4/abs/5050099a.html)
- 3-4. 'The Chinese pharmaceutical market: A strategic opportunity analysis' 2007. PharmARC: UK
5. Rosenberg M 2008, 'China Population', viewed 13 March 2008, <http://geography.about.com/od/populationgeography/a/chinapopulation.htm>
- 6-7. Yuanjia H, Geng F, Ying B & Yitao W 2007, 'The Chinese pharmaceutical market: Perspectives of the health consumer', *Journal of Medical Marketing*, 7, viewed 15 February 2008, [www.palgrave-journals.com/jmm/journal/v7/n4/abs/5050099a.html](http://www.palgrave-journals.com/jmm/journal/v7/n4/abs/5050099a.html)
- 8-11. 'The Chinese pharmaceutical market: A strategic opportunity analysis' 2007. PharmARC: UK
12. Xu C 2008, 'Global drug launches held back by Chinese regulatory backlog', *China Pharmaceuticals & Health Technologies Weekly*, IV, 19. Interfax: China
13. Taylor N 2008, 'SFDA crackdown to get house in order', *In-Pharma Technologist.com*, viewed 23 May 2008, [www.in-technologist.com/news/printNewsBis.asp?id=85287](http://www.in-technologist.com/news/printNewsBis.asp?id=85287)

### Disclaimer:

#### Forward Looking Statements

This publication contains certain forward looking statements. Forward looking statements are statements other than historical information or statements of current condition. These forward looking statements relate to the plans and objectives of the Company for future operations including the Company's plans for regulatory approval and its estimates for markets. In light of the risks and uncertainties inherent in all future projections, the inclusion of forward looking statements in this publication should not be regarded as a representation by the Company that the objectives or plans will be achieved.