



**Solagran Limited**

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18 July, 2007

### **Company Announcement**

#### **Pharmaceutical Registration of *Bioeffective® R* and *Ropren***

The Directors of Solagran Limited are pleased to announce that the Company has received formal documentation from the Russian Ministry of Health advising that pharmaceutical registration of both the substance *Bioeffective® R* and the medicine *Ropren* has been finalised.

The Directors regard this as a tremendous achievement after an intense four year effort. Solagran is now free to promote *Ropren* in Russia as a highly effective treatment for chronic liver disease.

Solagran will now focus on scaling up production facilities sufficient to meet the expected demand in Russia. It can also now initiate the next stage of its *Ropren* strategy which is to obtain pharmaceutical registration in the European Union as a precursor to taking it to North America and Asia.

#### **Strategy in Russia**

*Ropren* is a unique natural medicine. Its active ingredient *Bioeffective® R* is one of a family of 17 *Bioeffectives®* that Solagran's research team has developed over 30 years. Each has multifaceted activity and few if any side effects.

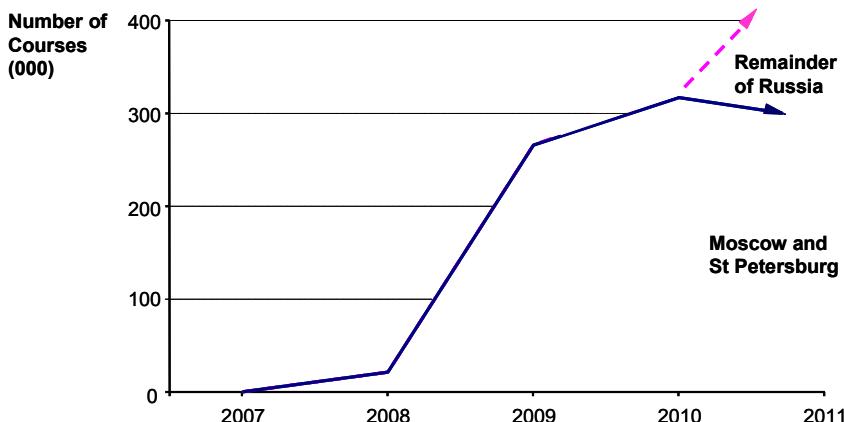
*Ropren* has been approved in Russia as a strong and effective natural hepatoprotector. Clinical trials have also demonstrated that *Ropren* has the potential to normalise lipid metabolism, strengthen the immune system, prevent and treat neurodegenerative disorders, and deal with conditions associated with drug and alcohol addiction.

The ability of *Ropren* to deal so effectively with chronic liver disease will have a very positive social impact in Russia. There are more than 10 million people with liver disease in Russia and the CIS countries, with up to 1 million new cases and 100,000 deaths each year.

Figure 1 illustrates Solagran's expectations in relation to the demand for *Ropren* in Russia. The Board expects demand for use in treating liver disease alone to reach 320,000 courses in 2010 and exceed 1 million courses per year by 2012.

Initially, the market is expected to be supply constrained, with Solagran only having capacity to meet the demand expected from hospitals and pharmacies in the cities of Moscow and St Petersburg.

**Figure 1.** Projected Demand for *Ropren* to Treat Liver Disease in Russia



### Production Capacity

The next step for Solagran is to obtain a manufacturing licence which will apply throughout Russia. This process involves obtaining approval firstly at local level, followed by state and finally federal level approval. It is a procedure that usually takes 2-3 months.

Solagran is already well advanced with the expansion of the SibEX plant in Tomsk into a facility capable of producing 20kg of *Bioeffective® R* per month by November 2007. This will translate into 60,000 courses of *Ropren* per year. Planning is also progressing in relation to the development of a new plant on SibEX land adjacent to the existing facility that will be capable of producing 100-200kg per month or 300-600,000 courses per year.

At least three additional production facilities are now planned for Russia to produce *Bioeffective® A*, *Bioeffective® V* and *Bioeffective® R*.

Beyond that, Solagran is looking to establish sites in Finland and in North America (potentially in either British Columbia or the Pacific Northwest).

An Executive Director has been appointed with primary responsibility for overseeing Solagran's global manufacturing capability.

### Strategy Beyond Russia

Solagran's current strategy involves firstly building a strong market position in Russia with *Ropren* and *Bioeffective® A*, and then using Russia as a base to take *Ropren* and other *Bioeffectives®* to the world.

Chronic liver disease is a significant global problem. In the US, it is estimated to affect around 4 million people with some 200,000 new cases, 300,000 hospitalisations and 30,000 deaths each year. Nevertheless, Solagran expects *Ropren*'s very real potential to prevent and treat neurodegenerative disorders (including Alzheimer's and Parkinson's diseases), together with its ability to normalise cholesterol levels, will have a particularly significant impact in that country over time.

While the intention is to obtain registration for *Ropren* in the European Union prior to pursuing FDA registration in the US, there is a possibility that both could be done in parallel. Enquiries have already been received from a considerable number of individual patients and their families in Europe and the US in relation to the availability of *Ropren* to treat both liver disease and neurodegenerative disorders.

At the same time, trials in St Petersburg are progressing well with both the injectable and liposomal forms of *Bioeffective® R*, as well as with *Bioeffectives® A, B and N*.

### In Summary

The Directors consider the registration of *Bioeffective® R* and *Ropren* to be by far the most significant milestone achieved by Solagran since it listed in 2003. Achieving full registration for a new and multi-faceted pharmaceutical substance of natural origin in less than four years is truly outstanding – particularly given the amount of change that was occurring within the Russian Ministry of Health during the time that Solagran's application was being processed. Normally, the approval process would take at least twice as long.

Shortcutting this process was only possible due to the outstanding efficacy and safety of *Ropren*, the stature and reputation of Solagran's Executive Chairman Dr Vagif Soultanov within the Russian medical research community, the professionalism and dedication shown by Solagran's project team in Russia led by Professor Victor Roshchin.

Registration opens the door for Solagran to begin to activate its global development strategy. When executed successfully, that strategy has the potential to create a whole new direction in medicine involving the use of highly effective but low side-effect natural *Bioeffectives®*.



Peter Stedwell  
**Company Secretary**  
On behalf of the Board of Directors  
Solagran Limited