Solagran Background

Solagran is an Australian company established in 1995 and listed on the Australian Stock Exchange in 2003. It owns a significant body of intellectual property related to the science of Forest Biochemistry and is named after the two scientists who initiated study in this field in 1931 at the St Petersburg Forest Technical Academy — Professor Fyodor Solodky and Dr Asney Agranat.

Forest Biochemistry is the science of extraction and utilisation of the “live elements” of green tree foliage. Solagran has collectively trademarked the proprietary biologically active substances it derives through the application of Forest Biochemistry as Bioeffectives®.

The first Bioeffective was extracted from green pine needles in the late 1930s. It played an important role in the survival of much of the population of Leningrad (St Petersburg) throughout a 900 day siege during World War II. That substance is now known as Bioeffective A, and over the past 70 years it has been the subject of more than 50 clinical trials involving some 6,000 patients aged from 7 to 84 years.

As a result of a continuous research effort spanning more than 75 years, Solagran now has a portfolio of 15 Bioeffectives derived from conifers, and a unique and patented extraction technology that gives it the ability to identify and extract different Bioeffectives from virtually any tree species or plant biomass.

Most Bioeffectives have multiple applications as natural pharmaceuticals with few if any side effects. Some can also be used as biologically active additives or agents in food manufacture, agriculture and animal husbandry. Solagran’s core family of 11 Bioeffectives is illustrated in Fig. 1 below.
Solagran Products

Having secured its intellectual property with a technology patent in Russia which is currently being expanded to cover seven key countries via the Patent Convention Treaty, Solagran has chosen to focus its initial commercialisation efforts on three Bioeffectives in four geographic regions. The Bioeffectives are A, B and R. The regions are Australia, Russia, North America and Scandinavia.

Bioeffective A

Bioeffective A is a product that is effective in many different applications. In February 2006, it was approved as a new complementary medicine substance by Australia’s Therapeutic Goods Administration.

As with many Bioeffectives, it is compositionally complex and contains a huge number of valuable biologically active components. The identity and nature of these substances, as well as their relative proportions, are determined by nature — not by Solagran. During the siege of Leningrad, Bioeffective A was used topically as a treatment for burns, wounds and frostbite, and internally as a treatment for colds, flu, bacterial infections and gastrointestinal disorders.

Extensive trials over many years have established that together, the substances that comprise Bioeffective A have the ability to enhance the immune system, help normalize haemoglobin levels, extract heavy metals and other pollutants from the body, eliminate many pathogenic micro organisms, and treat a range of gastrointestinal disorders.

Bioeffective A is a broad spectrum antimicrobial that is effective against many bacterial and fungal infections. A trial conducted in 2005 at the St Petersburg State Medical Academy compared Bioeffective A against two synthetic antibiotics (Erythromycin and Doxycycline), one antifungal (Amphotericin) and two natural substances (Echinacea and Bioeffective S). Eight reference strains of bacteria and one fungus (Candida Albicans) were used. Bioeffective A was able to inhibit the growth and reproduction of all reference strains. Even though the specific action of the antibiotics was stronger for certain pathogens, the broad activity spectrum of Bioeffective A coupled with its very low level of toxicity, makes it an ideal active for many medicines and personal care products. It remains shelf stable for many years without the need for preservatives.

A number of studies have shown that Bioeffective A is effective in both preventing and treating a range of gastrointestinal disorders. Strong phytocides plus other biologically active components enable Bioeffective A to speed up the healing of ulcers and erosions in various forms of gastritis and colitis. A trial conducted at the N.N. Petrov Oncology Institute in 1999 showed that a 3 month course of Bioeffective A was effective in treating elderly patients suffering from pre-cancerous chronic atrophic gastritis.

Bioeffective B

Bioeffective B is another compositionally complex substance which is applied topically — mainly in
conjunction with a sauna. It was first developed for use by Olympic boxers, weightlifters and wrestlers to help them to recover more quickly from the effects of competition and training. For the past two years, it has been used successfully by a leading team in the Australian Football League and is now being trialled by professional sporting teams in Scandinavia.

The use of Bioeffective B in conjunction with a sauna also has many potential applications in the consumer well being market — particularly in relation to stress reduction, skin rejuvenation and weight management.

Bioeffective R

Bioeffective R is a polyrenol. It was first isolated and extracted from conifer needles in the early 1980s by Solagran’s Research Director, Professor Victor Roschin. It is a unique substance that has many potential uses, including:

- Treatment of chronic liver disease including hepatitis and cirrhosis,
- Prevention and treatment of neurodegenerative diseases including Alzheimer’s and Parkinson’s diseases, and
- Strengthening and balancing the immune system.

Solagran has completed phased clinical trials for the use of Bioeffective R as a low side effect treatment for chronic liver disease. It is currently awaiting final regulatory approval from the Russian Ministry of Health. All medical approval processes were completed successfully in February 2006, and Solagran hopes to begin marketing Ropren (the final dose form of Bioeffective R) in Russia in the last quarter of 2006.

A 4-month-clinical-efficacy trial with Alzheimer’s patients was completed in St Petersburg in 2006. This trial pointed to a link between liver degeneration and a number of neurodegenerative processes, and among other positive findings, demonstrated the potential of treatment with Bioeffective R to restore cognitive function in patients with Alzheimer’s disease.

Fig. 3 shows the impact of Ropren treatment on cognitive function as measured by a standard Mini Mental State Examination (MMSE). The patients in the trial have been grouped according to the time since their condition was first diagnosed. All three groups of patients experienced a noticeable improvement in cognitive function after just 4 months of treatment. Some patients who had been diagnosed relatively recently were able to achieve almost full restoration of cognitive function.

Further trials are now underway in both Australia and Russia to better understand the ability of Bioeffective R to prevent and treat neurodegenerative disorders.
A series of trials have demonstrated the potential of Bioeffective R to enhance immune function. An animal trial conducted in 2005 demonstrated that a single dose of Bioeffective R prior to infection with the H2N3 Influenza A Virus led to a marked improvement in both mortality and morbidity rates. A subsequent clinical efficacy trial to understand the ability of Bioeffective R to improve resistance to flu infection in children will be completed by mid 2006.

The Market for Solagran’s Products

The market for all of Solagran’s products is extensive. A series of products based on Bioeffectives A and B will be launched in Australia during the second half of 2006. These products are illustrated in Fig. 4. All of these products or treatment regimes will compete in large and relatively attractive markets which could grow significantly once the efficacy of products containing Bioeffectives becomes apparent to health professionals and consumers.

The potential markets for the three main applications of Bioeffective R are very large. Russia has 10 million people suffering from chronic liver disease and 100,000 related deaths annually. Existing treatments are not particularly effective, have high side effects and are expensive. In the US, there are 4.5 million people with chronic liver disease and some 30,000 related deaths annually. But by far the largest market for an effective treatment for chronic liver disease is China.

Neurodegenerative disorders, and particularly Alzheimer’s’ disease, impose an enormous social and economic cost in developed countries where the disease is more
prevalent. The impact of Alzheimer’s disease on the US economy alone has been estimated to be US$100 billion per year.

There is a very large market for a pharmaceutical grade immunomodulator. There are few effective treatments for immune system dysfunction, and we have to rely on vaccines to boost specific immunity.

**Solagran’s Future**

Solagran’s technology represents a potential paradigm shift in the pharmaceutical industry, from a focus on single molecule, single application, synthetic substances, often with relatively high side effects; to multiple molecule complexes or *Bioeffectives* with multiple applications and few if any side effects.

Solagran’s strategic priorities for 2006 are to obtain TGA approval for *Bioeffective A*, Russian Ministry of Health Approval for *Bioeffective R*, to launch products in Australia in the second half of 2006 based on *Bioeffectives A* and *B*, and to begin selling *Bioeffective R* in Russia. TGA approval was received in February and final Russian Ministry of Health approval is expected in the next few months. So Solagran is well on the way to achieving all four milestones.