



## ASX RELEASE

28<sup>th</sup> December 2011

### **Viroxis Update**

The TFS Group is pleased to announce that it has entered into a number of agreements with two US Biotech companies ViroXis Corporation (“Viroxis”) and Santalis Pharmaceutical Inc (“Santalis”).

#### **Introduction**

Approximately two years ago TFS Corporation (TFS) was approached by a US Biotech firm, ViroXis Corporation (Viroxis) seeking assistance in the development of a pharmaceutical drug to treat HPV common warts in adults and children.

At that time Viroxis had successfully completed a phase II investigator sponsored clinical trial which was a proof of concept study involving Indian Sandalwood Oil (*Album*) treating HPV (Human papilloma virus) warts. This positive preliminary result led Viroxis to seek approval from the US Food & Drug Administration (FDA) through an Investigational New Drug (IND) application to advance its human clinical trial programme.

On the 8<sup>th</sup> April 2011, ViroXis ([www.viroxis.com](http://www.viroxis.com)) announced that the IND application was accepted by the FDA and it had been given approval to enter into commercial phase II clinical trials that are expected to commence later this year. Viroxis has advised TFS that the US FDA has insisted that a future phase III trial must use Australian sourced plantation oil (*Album*).

TFS considers this to be a highly significant event in the development of TFS’ Indian Sandalwood Plantation Estate, and the effort to develop demand for oil that results in higher global oil prices.

#### **Investment in Viroxis**

The approval of the IND for Viroxis to advance its human trial programme provides an opportunity for TFS to work with Viroxis to investigate other medical opportunities for sandalwood products. Some of these opportunities had already been explored by one of TFS’ wholly owned subsidiaries Mt Romance Australia.

As a result the two parties jointly funded some preliminary trials on alternative pharmaceutical related products containing sandalwood oil. After encouraging results the two companies have now agreed to formalise this development process.

In particular TFS has agreed to the following terms with Viroxis and its sister company Santalis–

- TFS has reconfirmed and upgraded the sandalwood supply arrangement with Viroxis on an exclusive basis to pursue commercialisation of treatments for topical viral skin diseases such as HPV warts
- In consideration for providing Viroxis with this exclusive supply arrangement, TFS has been issued a warrant (i.e. option) to purchase approximately 10% of the currently issued shareholding in Viroxis at a fixed price that can be exercised over a term of 7 years to November 2018. Should TFS fully exercise these warrants the investment by TFS would be \$1.5m
- The key shareholders of Viroxis have created a new vehicle – Santalis– to pursue research and commercial developments solely relating to Sandalwood and targeting all possible conditions outside of viral skin diseases. Preliminary testing suggests that Santalum Album contains a variety of pharmacological properties being; anti-inflammatory, anti-microbial, anti-fungal, and anti-bacterial. Research is currently in progress to advance the validation of these properties. TFS will take a 50% interest in Santalis with no direct consideration for the equity
- In exchange, TFS will commit to a long-term exclusive Indian sandalwood (*Album*) supply agreement to pursue commercial developments in the Western healthcare arena
- Further, TFS has agreed to underwrite funding to Santalis for the amount of up to US\$1.5m per annum for five years for its product development costs. The amount of funding provided by TFS is reimbursable from revenues received by Santalis in the future. TFS also has the right to withdraw from its underwriting obligation on an annual basis for any reason but as a consequence would hold a reduced interest in the shares of Santalis

These arrangements are designed to promote demand for Sandalwood oil in a new and potentially high volume high growth market sector and where TFS can influence the vertical supply chain. Viroxis estimates that over the long-term the global HPV common skin warts market could absorb up to 240 tonnes pa of TFS' Indian Sandalwood Oil (*Album*) supply.

By making this small investment into a distribution vehicle within the US healthcare sector, TFS aims to assert a positive influence on global Sandalwood oil prices and by extension related Sandalwood products.

The benefits for TFS shareholders in generating a higher global price of oil include –

- TFS benefits directly from a higher oil price via the value of its own plantation holdings increasing markedly
- TFS benefits from elevated marketing and performance fees from wholesale investors via delivering higher oil prices for its investment clients
- TFS benefits from wood acquired from its Retail investors to which it can then add value

### **US New Drug Application (NDA) Programme**

Regulatory guidelines provided by the US FDA state that phase III human trials involving Indian Sandalwood Oil (*Album*) need to be from a sustainable and ethical Australian source. As a result, Viroxis' phase III human trials will be aligned with the TFS harvest time line. Subsequently, Viroxis is enhancing its drug development program with a commercial phase II trial which the FDA has accepted.

TFS previously had a non-exclusive supply agreement with Viroxis that was conditional upon gaining regulatory approval for commercialisation of albuterpenoids, the drug that is derived from Indian Sandalwood Oil (*Album*).

Viroxis advises the phase II trial is expected to take about 18 months to complete, after which Viroxis intend to move into a phase III study as the final step before gaining FDA approval to take the product to market.

Viroxis' clinical experience with Sandalwood has provided optimism that the anti-viral activity and safety profile of Indian Sandalwood Oil (*Album*) could lead to a new treatment for a highly prevalent, painful and difficult to treat condition, for which there is essentially no approved prescription product. It has been estimated that 20 million people in the US are infected with HPV, making this a potentially significant market for TFS to supply into.

Viroxis aims to be among the first companies to gain phase II IND approval from the FDA for a botanically-derived topical drug. In 2004 the FDA implemented new guidelines aimed at streamlining the development of botanical drugs. The new drug is a mixture of plant-derived compounds rather than a single chemical entity.

Approval for the phase II study is the first step in a number of clinical developments that Viroxis is planning to pursue with the support of TFS as the critical supplier of oil for such initiatives.

TFS' supply contracts with Viroxis and Santalis have been struck well above current spot prices, indicating the substantial premium that is likely in the application of TFS' oil for the potential treatment of various human health conditions. The pricing terms of the agreements are also subject to CPI indexing each year and a pricing review every three years to at least maintain the current market price over the longer term which is the average weighted price sold by TFS or an affiliate company.

The continued success of the Viroxis development program encourages TFS' belief that the global healthcare market can be a significant source of new demand for TFS' plantation based oil where reliable supply is a key factor in driving high volume usage.

TFS also notes that Viroxis and the FDA have laid down strict guidelines in the specifications necessary to manufacture Pharmaceutical grade oil, which TFS has managed to meet in the IND application. This is likely to constitute technical and regulatory barriers into this market.

The recent results of the trial harvest of FPC trees indicate that TFS' plantations are on track to deliver substantial oil volumes to service the healthcare arena.

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## **ABOUT TFS**

TFS Corporation Ltd (ASX: TFC) is an owner and manager of Indian sandalwood plantations in the east Kimberley region of Western Australia. As part of its vision to be a vertically integrated producer of finished sandalwood products, TFS owns a significant proportion of the plantations in its own right and in 2008 acquired Mount Romance Australia (Mount Romance), the Albany-based sandalwood processor and oil distributor.

TFS was founded in 1997 to exploit the success of government trials into the plantation growth of Indian sandalwood in the Ord River Irrigation Area (ORIA) of north-east Western Australia.

TFS's first planting was in 1999 and it now manages the largest area of Indian sandalwood plantation in the world, with approximately 5,000 hectares planted. TFS plantations are managed on behalf of both retail and institutional investors.

The company listed on the Australian Stock Exchange in December 2004.

TFS is committed to adopting and maintaining the highest environmental and ethical standards in all aspects of its business. All plantations are grown on land that has previously been used for agricultural or horticultural production. As the first ORIA land owner to recycle its water, TFS was the winner of the 2006 State Regional Water Award.

In 2009, TFS entered the prestigious Forbes Asia Pacific's '*Best Under a Billion*', which recognises the Top 200 companies from more than 25,326 publicly-listed firms in the Asia/Pacific region with revenue of less than US\$1 billion.

## **ABOUT INDIAN SANDALWOOD**

Indian sandalwood has a history as a tradeable commodity spanning thousands of years, but is now endangered due to the illegal harvest of wild trees throughout the world. As a result, Indian sandalwood is the world's most expensive tropical hardwood and continues to increase in price each year. Its heartwood currently trades for in excess of A\$110,000 per tonne, having risen at a compounded rate of over 18% per annum over the past 18 years.

Indian sandalwood oil is a globally important ingredient in fine fragrances, cosmetics and toiletries, incense sticks, and for medicinal purposes (aromatherapy and Chinese medicine) and the wood is used for high quality carvings.

Indian sandalwood has a well entrenched market throughout the world, particularly in India and China, two of the fastest growing economies in the world.