



## **DEVELOPMENT PLAN FOR PTL-202, A TREATMENT FOR PROGRESSIVE ORGAN SCARRING, A \$1.1 BILLION OPPORTUNITY**

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Worldwide, there are over 5,000,000 people living with Idiopathic Pulmonary Fibrosis (IPF)(IPF Coalition). IPF therapy sales across the US, France, Germany, Italy, Spain, and the UK to rise to over \$1.1 billion by 2017, at a Compound Annual Growth Rate (CAGR) of 86.6% (RnR Market Research, 2013). IPF kills more patients per year than either prostate or breast cancer.

Pacific Therapeutics Ltd. (the "Company") lead drug candidate for fibrosis (progressive scarring of the organ), PTL-202 is a combination of Pentoxifylline (a FDA approved drug used for treating leg cramps) and N-Acetyl-Cysteine (NAC) an amino acid and an extremely potent and important antioxidant.

As previously announced the company has completed a phase 1 trial of the combination in humans. The positive results from the phase 1 clinical trial and positive pre-clinical results, will lead to further development of the product for treating fibrosis such as Idiopathic Pulmonary Fibrosis and Liver Cirrhosis.

### **Market Opportunity**

There are 218,000 sufferers of Idiopathic Pulmonary Fibrosis (IPF) in the United States of which 85,000 are diagnosed (Datamonitor, Aug 2005). An aging population combined with improved diagnostics will increase the diagnosed population by 40% to 146,000 by 2015 in the USA were 40,000 new cases of IPF are diagnosed annually (InterMune 2006). The primary sufferers of pulmonary fibrosis are in the older populations between 50-70 years of age.

The IPF therapeutics market in the US is predicted to grow to nearly \$500 million in 2015 and reach \$696m in 2017, a CAGR of 154%. In contrast, the European IPF market was valued at a far stronger \$43m in 2012, but is forecast to grow to \$419m in 2017 at a CAGR of 58% (RnR Market Research, 2013).

### **Clinical Development**

As previously announced data from the phase 1 trial showed a synergistic relationship resulting in an increase in the Active Ingredients of PTL-202 in the blood and an increase in known therapeutic effects without any new side effects. These results may improve the competitiveness and commercial potential of PTL-202. With the combined positive phase 1 clinical results and positive efficacy results from the pre-clinical testing of PTL-202 in animals with pulmonary fibrosis in hand, the company intends to proceed to a second clinical trial of PTL-202.

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A phase 1 clinical trial is usually intended to test for the safety and toxicity of a new drug being developed. In the case of PTL-202 a combination of approved drugs, the safety profile and toxicity are already well known as the individual active ingredients have been on the market for many years. The question is, if when given in combination, are there synergistic effects or new side effects? The phase 1 clinical trial of PTL-202 was designed to test for interaction between the Active Ingredients combined in PTL-202 for synergistic effects and new side effects.

The clinical trial provided definite evidence of synergy and will allow patients to take smaller doses improving the likelihood of marketing approval. Trial results showed that when given in combination, to healthy males, the amount of the Active Ingredients in the blood of the test subjects was much higher than if the same amount of one of the Active Ingredients alone had been given to the test subjects. In addition the known therapeutic effects such as vasodilation were also enhanced. The increase in known therapeutic effect was consistent with an increased amount of Active Ingredient in the blood. The good news is that the planned final dose in the end product may be much smaller than had originally been planned. This change will result in a smaller, easier to swallow pill and improved patient compliance, regulatory acceptance and potentially improved commercial potential.

Another positive result from the phase 1 trial was that no additional side effects were reported. The side effects such as dizziness and nausea were consistent with the higher amounts of the Active Ingredients from the combination that were in the blood at peak concentrations. This result may bode well for regulatory approval as no new side effects were evident.

The Company's proprietary once a day dosage will be more convenient for the patient and may improve efficacy as well as patient compliance. Given the positive synergistic effects indicated in the phase 1 trial, it is very important that the final dosage and formulation of PTL-202 be precise. If the ratio of Active Ingredients in the combination is not precise or the Active Ingredients are released into the body too quickly, the drug's effectiveness may be reduced or patients may not take their medication due to an increase in side effects. This requirement for precise delivery of the Active Ingredients provides a barrier to entry as it may prevent patients taking existing marketed formulations of the Active Ingredients to attain the same therapeutic effect. In addition none of the approved forms of the Active Ingredients are available as a once a day pill like the company is developing. Existing approved forms of the Active Ingredients are required 2 or 3 times a day and may release the Active Ingredients too quickly resulting in high levels of the drugs in the blood at one time increasing side effects. In addition the reduced chance of side effects may provide physicians with additional incentives to prescribe PTL-202. The planned unique slow release formulation and ratio of Active Ingredients will create an added barrier to competition over and above that provided by patent protection, improving commercial potential.

### **What's next?**

In addition to having completed the above successful clinical trial and pre-clinical studies the once a day formulation of PTL-202 has been completed. The next step is to use the results from the phase 1 study to fine tune the amount of Active Ingredients in the final formulations. The fine tuning of the dosage will lead to a regulatory filing, potential dose ranging and proof of principal clinical trial. Data from a proof of principal trial may lead to sale of PTL-202 to a commercialization partner.

## **ABOUT PACIFIC THERAPEUTICS LTD.**

Pacific Therapeutics Ltd is a clinical stage specialty pharmaceutical company focused on the identification and development of drug candidates suitable for reformulation and repurposing. Its lead programs focus on erectile dysfunction and diseases of excessive scarring (fibrosis).

In 2011 the total market for drugs to treat erectile dysfunction (“ED”) exceeded \$5 billion. Pacific Therapeutics Ltd. has finalized a definitive agreement to license an oral dissolving technology (“sublingual formulation”) of an approved drug to treat erectile dysfunction (ED).

Sales of the market leader alone exceeded \$1.9 billion in 2011. The sublingual formulation improves on existing drugs for erectile dysfunction potentially acting faster and with fewer side effects. As large pharmaceutical companies lose their patents on these drugs the opportunity has developed for innovative formulations of drugs for ED. This is a very exciting development for Pacific Therapeutics Ltd. as it shortens the time to market for the Company’s first product and may add significantly to future revenues.

Utilizing funds from the previously announced private placement the Company will build on the already significant development of the sublingual treatment with the initiation of a pivotal Bioequivalence trial. This is the last trial that needs to be performed prior to application for marketing approval. The trial will enrol 24 individuals and only take 4 months for completion. With successful results from this trial the Company will begin the application for marketing approval.

The Company’s strategy includes reformulating approved drugs to increase efficacy and patient compliance, while reducing side effects, as well as completing the further clinical testing, manufacturing and other regulatory requirements sufficient to seek marketing authorizations. This strategy may reduce the risk, time and cost of developing therapies by avoiding the risks associated with basic research and using compounds with unknown safety and toxicity profiles.

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## **FORWARD LOOKING STATEMENTS**

Certain statements included in this press release constitute forward-looking information or statements (collectively, “forward-looking statements”), including those identified by the expressions “anticipate”, “believe”, “plan”, “estimate”, “expect”, “intend”, “may”, “should”, “possibly” and similar expressions to the extent they relate to the Company or its management. The forward-looking statements are not historical facts but reflect current expectations regarding future results or events. This press release

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contains forward looking statements. These forward-looking statements are based on current expectations and various estimates, factors and assumptions and involve known and unknown risks, uncertainties and other factors.

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