



## NEW DRUG DELIVERY PLATFORM ACQUISITION

FOR IMMEDIATE RELEASE

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- Means to gain patent exclusivity over off-patent blockbuster drugs
- Unprecedented multi-billion revenue potential for a small-cap biotech company

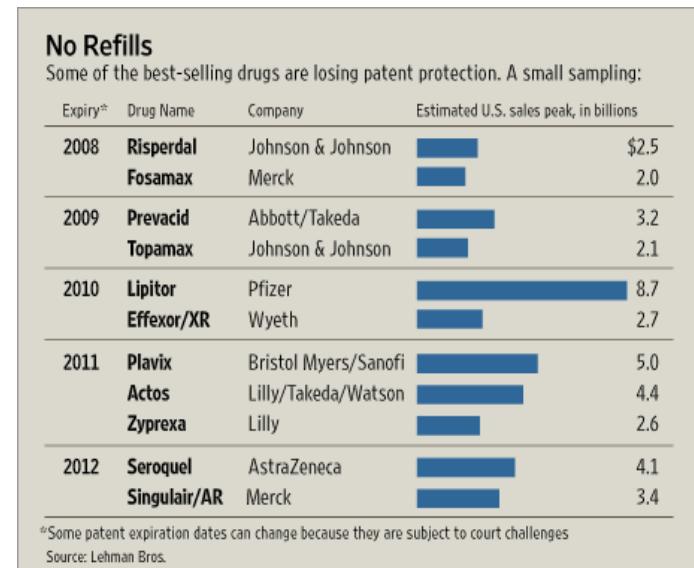
Australian healthcare company Stirling Products Limited (ASX:STI) advises that the Company and Zodiac Capital Limited, its joint venture partner in pharmaceutical and botanical products, have entered into a Heads of Agreement (HOA) with Sheiman Ultrasonic Research Foundation Pty. Ltd. to acquire the rights to and commercialise a patented new class of aerosol generation devices with the capability of becoming a breakthrough drug delivery platform.

Initial validation and independent testing of drug administration using prototype demonstration devices has shown this High Density Aerosol ("HDA") technology to be highly efficient and effective in delivering drugs via inhalation. The major benefit of HDA drug administration is that it promises to provide the same efficacy as drugs taken orally, with far less active drug content which, subject to formal trial validation, should therefore increase drug safety and substantially lessen any side effects.

The HDA technology offers a significant opportunity for the Stirling Products joint venture to target a multi-billion revenue market as it leverages its new technology to improve the safety profile of and thereby have

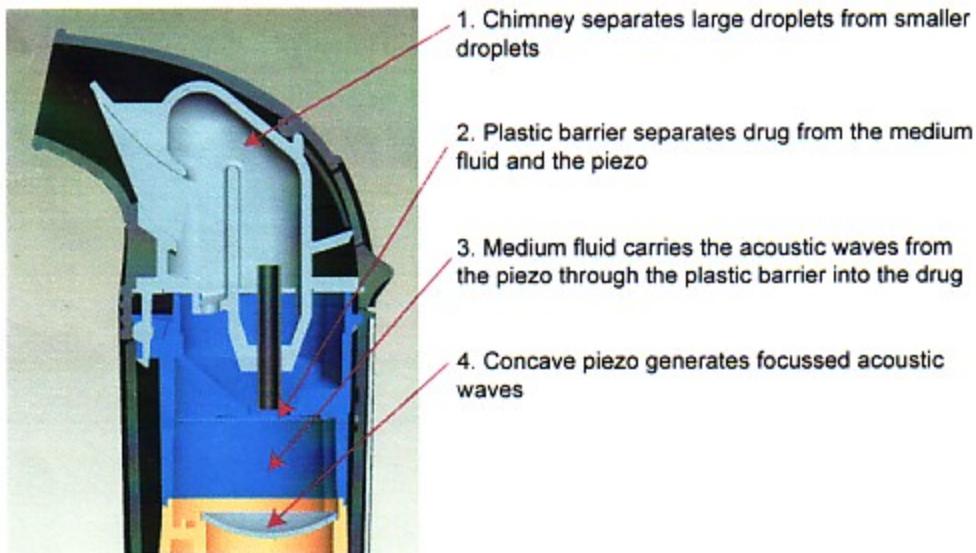
the equivalent of or rights to a new patent to the improved performance version (subject to trial validation) of some of the world's major drugs as they come off patent. This is particularly relevant as in the five year period to 2012 over 36 major drugs will have come off patent which is expected to lower yearly product sales of the major pharma's by around US\$67 billion in the US alone, and more than double this amount globally.

*The HDA device is patented internationally and opens up many new possibilities for both medical and non-medical applications of aerosols. The technology offers valuable benefits over conventional technologies.*



An early, single-dose nebuliser using the Sheiman Ultrasound Research Foundation HDA technology device achieved 510K approval by the US FDA and is shown for illustrative purposes. The new devices will incorporate newly patented technologies and capabilities.

*HDA technology illustration*



Due to the unique performance characteristics of this technology, the HDA device is better suited to delivering a wide variety of drug applications in a more optimised and efficient manner than through oral drug administration or currently available nebulisers.

The HDA technology uses focused ultrasonic energy to form a fountain of liquid to be nebulised that produces an aerosol from the walls of the jet that self-propels at several meters per second up a chimney-like intake tube. Atomisation of the liquid occurs at the base of the jet inside the intake tube. The micro-particle aerosol is then transported to the user by positive dynamic pressure derived intrinsically from the kinetic energy of the jet. The HDA technology therefore does not require any compressed gas or fan driven airflow to transport aerosol to the user. This significantly increases the aerosol concentration by both eliminating the gas/fan dilution effect and reducing the drug loss associated with aerosol condensation inside the nebulisation chamber.

**Key features of the HDA technology are:**

- Drug transportation velocity is matched to the patient's natural inhalation
- Aerosol losses due to deposition on drug delivery pathways are reduced
- Delivers at least three times the aerosol concentration of conventional ultrasonic devices
- Provides a concentration level between that currently achieved with dry powder inhalers and conventional fan driven nebulisers.

- Delivers the drugs with much faster absorption and much lower transportation losses.
- Constant aerosol concentration during inhalation is adapted to natural patient breathing
- The active drug particle size is sub-5 micron, providing for better and more rapid absorption
- Active drug is in unique disposable capsules further **protecting against competition**
- Compared to oral administration, testing has shown **substantively LESS active drug** could be required **to provide the same benefit** therefore also potentially **increasing safety and lessening side effects**
- Can potentially be used for administration of most drugs

Additionally, the HOA provides for the inclusion and incorporation of a new revolutionary Dynamic Mesh technology being separately patented (pending). This Dynamic Mesh technology offers the specific benefit of delivering a tightly controlled **micro particle size e.g. < 5 microns** which is achieved by restricting the larger particles as they attempt to pass through the mesh. A critical limitation of existing devices is a significant problem with clogging which can prevent accurate dosing and use generally.

The combination of electronic particle size control with the self cleaning Dynamic Mesh technology further enhances the benefits of the HDA drug delivery platform and its capabilities.

### **Application and Potential of HDA Technology in the Drug Market**

The first focus of the Company will be to finalise pre-production HDA devices which will then be trialled with applications for some of the world's leading off patent drugs to validate the technology as being able to provide a safer user profile without the loss of any efficacy.

Pulmonary delivery of drugs was until recent years largely used exclusively for respiratory disease, but is now the subject of intense interest as inhalation products emerge for non-respiratory conditions such as diabetes and migraine. Some of the major companies that are actively pursuing technological advances within the pulmonary delivery sector include: Alkermes Inc., Aradigm, AstraZeneca Plc, Baxter Healthcare Corporation, Bespak Europe, Chiesi Farmaceutici SpA, Dey L.P., GlaxoSmithKline, Inyx Inc., LAB International Inc., Nektar Therapeutics, Oriel Therapeutics Inc., Sepracor Inc., SkyePharma Plc, Vectura, and Ventaira Pharmaceuticals.

The HDA technology demonstrates fully patent protected technological advances that are now positioned for commercial production and application. An example of the Company's potential to leverage this situation can be illustrated with the blockbuster statin products that are recently off-patent or very close to. This drug group has often come under attention, especially with regard to their side effects. With the HDA technology devices providing technology that will deliver the same beneficial effect with far less active drug content, the safety profile is expected to be substantively improved and thereby assuring less side-effect for users. With a current global market for Lipitor, the industry's lead statin product at around US\$13 billion per year, and for Crestor US\$2.75 billion and both coming off patent in the next two years with Zocor already off-patent, this HDA application, in just statins alone, can represent a massive

opportunity for the Company, even if it can only pick up 10% of the global market through what promises to be a safer profile drug administration. Similarly, for the well understood inhalation asthma drugs, Advair, Seretide, and Singulair that are also coming off-patent and have combined annual sale of around US \$11 billion, it would not be unreasonable to target achieving 20% of this market within five years. These opportunities continue throughout the varied medical conditions that have been the subject of treatment by drugs either recently off-patent or in the process of going off-patent in the next few years.

#### **Application to Stirling's Botanical Products:**

As well as the HDA technology application as a new drug delivery platform, the Company now also has the opportunity to use it as an added and effective delivery platform for its botanical products. One of the first development objectives will be a Stirling Products HDA aromatherapy device for use in conditioning air in homes, workplaces and schools with the Company's ImmunoXel which may also be beneficial in boosting the immune system of all occupants.

Stirling Products Managing Director, Mr Peter Boonen, stated: "This HDA technology is absolutely unique in its effectiveness and potential and will provide a platform for the Company to substantially enhance its own product lines and also to leverage the technology into some of the world's most valuable drugs that are off-patent or coming off-patent. Through this technology we can have the benefits equivalent to a new patent on each of the off-patent candidates that we undertake, as the HDA technology has demonstrated its promise to improve their respective performance and safety many times over."

This transaction, which the Company has been working on for the past three to four months, provides a key cornerstone to the positioning of the Company interests as a serious emerging player in a global pharmaceutical industry that is rapidly undergoing quite dramatic change. The opportunity, that we now have with Stirling Products for having exclusivity over the numerous off-patent blockbuster drugs with their performance and safety profiles enhanced through the HDA technology is, we believe, unique and unmatched in the pharmaceutical industry."

#### **HOA Terms and Conditions:**

The key terms of Agreement between the Company, Zodiac Capital and the Sheiman Ultrasonic Research Foundation provide for the Company and Zodiac Capital to each pay \$250,000 in cash or shares within seven days and for the Stirling/Zodiac joint venture to provide for all the staged funding costs of the commercialisation process commencing immediately. The first process stage shall be the HDA device pre-production development and also the application of the HDA technology to the Company's JV botanical products which has budgeted costs of a total \$570,000 over the next 12 months. The human and animal drug delivery platform development work is planned to commence in approximately six months from date of agreement but no later than 12 months and is conditional upon the arrangement or provision of a working budget of \$5-6 million which is intended to be secured through a series of grants within this 12 month period. The Sheiman Ultrasonic Research Foundation will retain an undiluted 35% interest in the HDA device(s), a 35% interest in all off-patent drugs that can be adapted for

use in the new platform, subject to all regulatory approvals that may be required for such use, and a 5% interest in any of the Company's products that are adapted for use through the technology.

**The Sheiman Ultrasonic Research Foundation** was founded in 1994 by Dr. Vladimir Sheiman following his immigration to Australia. In the Soviet Union he was a leading research scientist and the head of the Ultrasonic Laboratory in All-Union Research Institute of Medical Engineering, the biggest research organization in the Soviet Union in the field of medical engineering. Dr. Sheiman has spent a lifetime working with ultrasonics and is responsible for numerous patents in the field.

Following finalisation of agreement with the Stirling joint venture, Dr. Sheiman stated: "We look forward to the commercialisation of our HDA technologies with the Stirling Products group and implementing the strategy plan that we have been working on jointly for the past several months. We welcome this great opportunity to use our technology in the manufacture of drug delivery devices that we believe can exclusively provide for the better delivery and safety of many drugs, especially the established blockbusters as they come off-patent. We will also focus on using our technology to improve the application options for Stirling's product range."

**For further information see [www.stirlingproducts.net](http://www.stirlingproducts.net) or contact:**

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