

# FOR IMMEDIATE RELEASE

## DRUG DELIVERY PLATFORM ACQUISITION AGREEMENT FINALISED

....Acquires rights to breakthrough proven drug delivery platform technology ....Unprecedented multi-billion revenue potential for drug delivery of off-patent blockbuster drugs through potentially improved safety profiles

Sydney NSW, 23 October 2009 -- Zodiac Capital Limited (NSX: ZOD) is pleased to advise that the Company and Stirling Products Limited, its joint venture partner in pharmaceutical and botanical products, have entered into a final Agreement with Sheiman Ultrasonic Research Foundation Pty. Ltd. Under the Agreement, the Stirling/Zodiac joint venture has acquired the rights to commercialise a patented new class of drug inhalation devices that represent a breakthrough platform in drug delivery.

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 drug administration through the HDA technology 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.

Expiry*	Drug Name	Company	Estimated U.S. sales peak, in billions
2008	Risperdal	Johnson & Johnson	\$2.
	Fosamax	Merck	2.
2009	Prevacid	Abbott/Takeda	3.
	Topamax	Johnson & Johnson	2.
2010	Lipitor	Pfizer	8.
	Effexor/XR	Wyeth	2.
2011	Plavix	Bristol Myers/Sanofi	5.
	Actos	Lilly/Takeda/Watson	4.
	Zyprexa	Lilly	2.
2012	Seroquel	AstraZeneca	4.
	Singulair/AR	Merck	3.

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 exclusively use this safer profile of some of the world's major drugs as they come off patent. This is particularly relevant as in the five year period from 2007 to 2012 over 36 major drugs will come off patent which is expected to lower yearly product sales of the major pharmas in the US by around US\$67 billion, and more than double this amount globally.



An early, single-dose nebuliser using Sheiman Ultrasound Research Foundation HDA technology device has previous 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



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 and 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 transport velocity matched to the patient's natural breathing
- Reduced aerosol losses less deposition on drug delivery pathways
- 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.



- Active sub-5 micron drug particle size provides for better and more rapid absorption
- Active drug is in unique disposable capsules further protecting against competition
- Compared to oral administration, testing has shown <u>substantively LESS active drug</u> could be required <u>to provide the same benefit</u> therefore also potentially <u>increasing safety and lessening</u> side effects
- Can potentially be used for administration of most drugs

The Agreement between the parties 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 <u>micro particle size e.g. < 5 microns</u> 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.

Zodiac Capital Managing Director, Mr Peter Boonen, stated: "This HDA technology is absolutely unique in its effectiveness and potential. It will provide a platform for the Company to potentially 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 effectively have the exclusive rights to, subject to trial validation, the improved version of each of the off-patent drug candidates that we undertake. This potential opportunity for having exclusivity over numerous off-patent blockbuster drugs with the HDA version potentially having their performance and safety profiles enhanced is unmatched in the pharmaceutical industry."

#### **Agreement Terms and Conditions:**

The key terms of Agreement between the Company, Stirling Products and Sheiman Ultrasonic Research Foundation provide for the Company and Stirling Products to each pay \$250,000 (which payment has been satisfied by the respective issue of shares) and for the Stirling/Zodiac joint venture to provide for all the staged funding costs of the commercialisation process commencing immediately. The first stage over the next 12 months shall be the pre-production development of the first HDA devices which has budgeted costs of circa \$600,000. The testing of targeted major off-patent drugs for human use using the HDA inhalation devices is planned to commence in approximately 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 that the Company expects to have in place by that time.



The Sheiman Ultrasonic Research Foundation shall receive 35% interest in the gross profits derived from the sale of all HDA devices, 35% of gross profits from the sale of any or all off-patent drugs adapted for use in the new HDA platform, subject to regulatory approvals that may be required for such use, and 5% of the gross sales profits of the Company's joint venture 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.

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# COMMERCIAL OPPORTUNITY OF HDA DRUG DELIVERY PLATFORM

Further advice with regard to the Company's "Unprecedented multi-billion revenue potential for drug delivery of off-patent blockbuster drugs through potentially improved safety profiles" commercial opportunity is as follows:

There are many types of nebulisation and inhalation devices on the market today. The Company is not aware of any or any other technology that has the capability of delivery <u>for multiple individual drugs</u> in essentially a concentrated atomised liquid form of sub-5 micron particles. Further, as the actual delivery of the HDA technology devices through its piezo generated kinetic energy is regulated to the actual patient breathing, then the administration of any drug becomes far more user friendly and efficient. This would particularly be the case for young children and the elderly – a further market opportunity that will be addressed in the future.

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 drug administration through the HDA technology 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.

As advised within today's release - The HDA technology offers a significant opportunity for the Zodiac Capital/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 exclusively use this safer profile of some of the world's major drugs as they come off patent. This is particularly relevant as in the five year period from 2007 to 2012 over 36 major drugs will come off patent which is expected to lower yearly product sales of the major pharmas in the US by around US\$67 billion, and more than double this amount globally.

For further clarification, the Company's immediate focus and objective is to produce a limited number of pre-production HDA devices within the next 12 months which will then be used in preliminary equivalency, efficacy, safety and performance trials in order to establish the improved safety profile of the use of the HDA inhalation devices. These trials are fully expected to confirm the preliminary but limited trials performed to date using the original proto-type devices.



The Company's HDA technology has potential application to many of the world's leading drugs that are either recently off-patent protection or especially in the period to 2012, coming off patent protection. Around 30-40 of these drugs, under patent protection either have or have had global sales of within the US\$2 – 15 Billion each per annum. For example the global market for just the respiratory disease products is around US\$22 Billion with the majority of products either recently or soon being off patent.

As products go off patent they are then essentially in a free-for-all generic market and generally their respective price to market substantially decreases. It is within this market that the Company has its unique and unprecedented opportunity. As, to date there have been no regulatory trials of product using the HDA technology platform, the Company advises that <u>its opportunity is subject to the establishment of at least equivalency regulatory approvals, but will be seeking to achieve efficacy equivalent with improved safety profiles.</u>

In the example of the US\$22 Billion respiratory disease market above, the conservative potential of the HDA technology was assessed at 3% of the market – US\$660 Million per annum. This assessment was included in a comprehensive Market Evaluation Report prepared for Sheiman Ultrasonic Research Foundation and formed part of the Company's due diligence review of the HDA opportunity. Similar market and revenue opportunities exist within other disease sectors of the market.

Overall, the HDA device technology is extensively patent protected with a suite of existing issued patents. The technology is fully proven and market ready. The HDA technology inhalation devices are not intended to be licensed out but rather to be developed as a preferred delivery mechanism aimed for use by the Company's future pre-packaged generic drugs which in general would be contract manufactured. <a href="Importantly">Importantly</a>, the approval of any use of any prescription drug through the future HDA devices is subject to validation by regulatory trials where in the least equivalency would be required to be established but optimally improved safety. It should be noted however that these trials in many cases are expected to be of relative short duration and cost.

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