SUDA LTD Signs Option to Acquire NovaMist™ Sub-Lingual Platform Technology

Highlights:

- NovaMist™ technology provides a platform for a broad range of future products and licenses.
- Several projects in the pipeline including an oral spray version of Viagra (Duramist™).
- Over 79 granted patents and 90 patents pending worldwide.
- NovaMist™ technology already tested and accepted in the marketplace with 2 products, NitroMist™ and Zolpimist™ having been commercialised.
- SUDA has pre-emptive rights on commercialised products.

The Board of SUDA LTD (SUDA) is pleased to announce that it has signed an option to acquire a platform technology “NovaMist™” and a product pipeline from US drug company NovaDel Pharma Inc. (NovaDel). NovaDel is a specialty pharmaceutical company involved in developing oral spray formulations for a broad range of marketed therapeutics.

The NovaMist™ technology, like other sub-lingual delivery models, enables rapid delivery of drugs directly into the bloodstream which may result in faster onset of action and potential patient benefits in compliance, convenience and safety. In addition, the sub-lingual delivery model used by a number of companies, including NovaDel, offers safety benefits due to the fact that patients can receive a smaller, measured dosage of active pharmaceutical ingredient without compromising efficacy.

Importantly, NovaMist™ is protected by multiple layers of patents. Currently, NovaDel has more than 79 patents issued worldwide and over 90 patents pending around the globe. Within these patents there is an expansive database of potential products that cover a wide range of drug types and formulations that SUDA believes can become the basis of future products and product licenses.

These patents protect the development of solutions employing appropriate polar or non-polar solvents to constitute a formulation for the delivery of pharmaceutical products via spray to the oral mucous membranes. They further extend the application of this technology across numerous therapeutic areas and product categories. This protection would enable SUDA to develop oral spray formulations of many drug products, both hydrophilic and lipophilic, which will not violate existing process patents.
The NovaMist™ platform can provide either a valuable life cycle extension strategy for innovators whose products are facing patent expiration or new product development opportunities for companies wishing to develop their own brand of a competitor’s drug that is approaching expiration of its composition-of-matter patent.

NovaDel has the following products in various stages of development (more detail is attached at the end of the announcement).

- **NitroMist™** for angina is currently registered, licensed and marketed in the USA and Europe.
- **Zolpimist™** for sleep disorders is currently registered, licensed and marketed in the USA and Europe.
- **NVD-201** (oral spray formulation of sumatriptan, being developed for the treatment of migraine headache); (Phase 2/3).
- **Duromist™** (an oral spray formulation of sildenafil, being developed for the treatment of erectile dysfunction); (Phase 1/2).
- **Zensana™** (an oral spray formulation of odansetron, being developed for the treatment of chemotherapy-induced nausea and vomiting); (Pre-Clinical).
- **NVD-101** (oral spray formulation of sildenafil being developed for the treatment of Pulmonary Arterial Hypertension); (Pre-Clinical).
- **NVD-301** (an oral spray formulation of midazolam, being developed for sedation during diagnostic, therapeutic, and endoscopic procedures); (Pre-Clinical).

Under the agreement with NovaDel, SUDA has an option to acquire the NovaMist™ technology platform and all associated agreements and trademarks as well as the following 5 current product candidates that are at various stages of clinical development: Duromist™, NVD-201, Zensana™, NVD-101 and NVD-301. Further to this, SUDA will take ownership of all existing data in relation to the work carried out on the above products and materials that NovaDel had purchased in readiness for the next Duromist™ clinical trial.

The commercial potential of the NovaMist™ technology has been confirmed in the marketplace as NovaDel has two products: NitroMist™ for angina and Zolpimist™ for sleep disorders currently registered, licensed and marketed in the USA and Europe. Whilst these two products are not included in the current agreement NovaDel has granted SUDA pre-emptive rights over both NitroMist™ and Zolpimist™.

The commercial terms of the offer are subject to confidentiality at this time and the offer is subject to the satisfactory completion of due diligence. SUDA will have 45 days to complete the due diligence and, upon completion, SUDA has 90 days to complete the transaction.
SUDA’s Executive Chairman, Stephen Carter said: “The NovaDel transaction is the latest in a number of key changes, such as the change in name and two year $7.6 million funding arrangement, that the Directors of SUDA have put in place to add further value to the company. The Directors believe that these actions along with the fact that we are awaiting the results of our Phase III ArTiMist™ clinical trial, will help to address the current inequity in the market capital of SUDA against companies at similar stages in development.”

The Board thanks our shareholders for their continued and ongoing support.

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Product Candidates

**Duromist™**

Duromist™, an oral spray formulation of sildenafil, is being developed for the treatment of erectile dysfunction. Sildenafil is the active ingredient in Viagra®, a leading prescription medication for the treatment of erectile dysfunction, marketed by Pfizer. We believe that an oral spray version of sildenafil may afford faster onset of therapeutic action, and may allow for a lower dose compared to tablets.

The preclinical work has been completed, and a prototype formulation with satisfactory stability has been developed. In July 2010, NovaDel initiated a non-IND pilot pharmacokinetic, or PK, clinical trial comparing Duromist™ to Viagra. The trial was designed to assess the relative bioavailability and safety of one, two and three doses of 10mg/0.12ml of Duromist™, compared to that of the 25mg Viagra tablet. The trial was a single-center, open-label, single-dose, randomized, four-period, four-treatment, crossover study under fasting conditions. The total number of healthy adult male subjects enrolled in the study was 24.

In October 2010, NovaDel announced positive data from this trial. The data demonstrated that the 20mg dose (two sprays) of Duromist™ is bioequivalent to the 25mg Viagra tablet with respect to systemic exposure. Duromist™ demonstrated an excellent safety profile and was well tolerated in the pilot PK study.

**Zensana™**

Zensana™ is an oral spray formulation of ondansetron. Ondansetron is the active ingredient in Zofran®, a leading prescription medication for the treatment of chemotherapy-induced nausea and vomiting, marketed by GlaxoSmithKline (GSK).

NovaDel has entered into a number of licensing agreements for Zensana™ and these will be reviewed as part of the due diligence.

**NVD-201**

NVD-201 is an oral spray formulation of sumatriptan. Sumatriptan is the active ingredient in Imitrex®, a leading prescription medication for the treatment of migraine headache, marketed by GSK. NovaDel has completed a series of pilot pharmacokinetic clinical trials evaluating multiple doses of NVD-201 given to healthy adults.

The results from these trials demonstrated that NVD-201 was well tolerated, achieved plasma concentrations in the therapeutic range, achieved a statistically significant increase in absorption rate when compared with Imitrex® tablets, and achieved up to a 50% increase in relative bioavailability in comparison with Imitrex® tablets. In September 2008, they announced the results from a pilot efficacy study for NVD-201.

NovaDel believes this trial demonstrates that treatment with NVD-201 is safe and effective in relieving migraine headaches at a dose lower than that for sumatriptan tablets.

**NVD-301**

NVD-301 is an oral spray formulation of midazolam. Midazolam is a leading prescription medication used for sedation during diagnostic, therapeutic and endoscopic procedures. NovaDel believes that NVD-301 has the potential to be an easy-to-use, rapid onset product, useful in the relief of pre-procedure anxiety suffered by many patients prior to undergoing a wide variety of procedures performed in hospitals, imaging centers, ambulatory surgery centers and dental offices.