SUDA LTD

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ASX Release

NovaDel Shareholders Approve Suda Acquisition of NovaDel Assets

Acquisition of NovaDel Assets: Update

Suda Ltd is pleased to announce that the shareholders of NovaDel Pharma Inc. have approved the sale of assets to Suda.

On 8 April 2013, Suda advised that the Sale and Purchase Agreement was subject to appropriate statutory approvals. Following the successful outcome at NovaDel's Special Meeting held on 19th July, Suda advises that all conditions relating to the acquisition have now been met and that it will move to finalisation of the acquisition which is expected to occur within the next 10 days.

On settlement, NovaDel's core technology, NovaMist™ (to be renamed SudaMist™) will be transferred to Suda and the various projects in development phases form the basis of Suda's pipeline projects.

Post settlement, the Suda **R&D pipeline**, with product description and size of market is:

PROJECT	ACTIVE PHARMACEUTICAL INGREDIENT	DEVELOPMENT STATUS	INDICATION	GLOBAL MARKET SIZE *	CURRENT AVAILABLE DOSE FORMS
ArTiMist™	Artemisinin	Completed Phase III	Malaria		IV, IM, tablet, suppository
DuroMist™	Sildenafil citrate	Completed a non-IND pilot clinical trial (Demonstrated bioequivalence)	Erectile Dysfunction	US$4.1bn	Oral tablet
SUDA - 001	Sumatriptan	2 pivotal clinical trials	Migraine headache	US$200m in USA alone	Tablet, injection and nasal spray
SUDA – 002	Ondansetron	Completed clinical trials for registration under the FDA section 505(b)(2)	Chemotherapy induced nausea and vomit	US$3.6bn in 2015	Liquid and solution for IV, IM, syrup, oral tablet, oral disintegrating tablet, oral film and suppositories.
SUDA - 003	Midazolam	Completed formulation	Pre-procedural anxiety	US$150-170m	IV, IM, continuous infusion and buccal liquid
SUDA – 004	Sildenafil Citrate	Completed formulation	Pulmonary Arterial Hypertension	US $3.6B in 2015	Tablet, injection

Source: IMS Health reports

Summary of Status of Key Projects

DuroMist™ - Erectile Dysfunction

In October 2010, NovaDel completed a non-IND pilot pharmacokinetic 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 a 25mg Viagra® tablet.

The data from the clinical trial demonstrated that the 20mg dose (2 sprays) of DuroMist™ is bioequivalent to the 25mg Viagra® tablet.

Sumatriptan - Migraine

Two clinical trials were conducted to evaluate Sumatriptan lingual spray (LS) administration. The objectives of the trials were: (1) to determine whether Sumatriptan can be absorbed across the oral mucosa, and, if so; then (2) to describe its pharmacokinetics (PKs); and (3) to investigate whether there are pharmacodynamic correlates of such PKs in patients experiencing migraine attacks.

Clinical results indicate that Sumatriptan LS at doses of 30mg and 40mg may be significantly more effective than the 50mg Sumatriptan tablet in reducing pain and other symptoms associated with migraine headaches and produce a degree of relief that is qualitatively similar to the 100mg Sumatriptan tablet.

Ondansetron – Chemotherapy Induced Nausea and Vomiting (CINV)

ZondaMist™ is the first oral spray of Ondansetron (Zofran®), the most commonly prescribed antiemetic for CINV, radiotherapy-induced nausea and vomiting, and postoperative nausea and vomiting. This spray achieves therapeutic drug levels by delivering a micro-mist of concentrated Ondansetron over the oral mucosa and may offer a desirable alternative to patients requiring antiemetic therapy who have difficulty in swallowing.

Data from 4 studies confirmed that Ondansetron 8mg dose is statistically bioequivalent to the current commercially available 8mg Ondansetron tablet, is well tolerated and can be conveniently administered in multiple doses.

Midazolam – pre-procedural anxiety

An initial formulation has been completed, ready to initiate a pharmacokinetics study.

Sildenafil Citrate – Pulmonary Arterial hypertension

An initial formulation has been completed, ready to initiate a pharmacokinetics study.

Acquisition Price

The acquisition price of the NovaDel Intellectual Property is broken into 3 components:

1. Cash — US$400,000
2. Shares — 50,000,000 shares to be issued on closing
3. Options — 10,000,000 unlisted options to be issued on closing with exercise price at 5 cents, expiry date 31 December 2015.

This issue of shares and option received Suda shareholder approval at Suda's General Meeting held on 27th June 2013.

Suda's Executive Chairman, Stephen Carter, commented that "the NovaMist™ acquisition has taken 7 months to complete and the Suda Board is very excited to have been able to acquire both a pipeline of projects and the potential of the related NovaMist™ intellectual property platform and patents. Suda is no longer a single-product company. At the conclusion of settlement Suda will offer shareholders and potential investors a robust product portfolio with significant potential to progressively capitalise on our investment via out-licensing or trade-sale. In conjunction with consultants, we are currently finalising a comprehensive project development plan to prioritise each potential product candidate based on technical merit, size of market and competitive analysis. This will allow us to mitigate any development risk and optimise commercial returns."

Stephen Carter also referred to a recent announcement for the agreement for a Sumatriptan nasal spray: "As an example of potential sale and value of the NovaDel products, Avanir Pharmaceuticals agreed to pay OptiNose $20 million upfront and promised up to $90 million in milestones for the North American development rights for a new nasal delivery therapy of Sumatriptan. This therapy is similar to the Sumatriptan product that Suda will develop and gives an indication of the potential of this IP that Suda is acquiring."

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About NovaDel's assets

NovaDel's core technology utilises a proprietary system, NovaMist™, to deliver a broad range of marketed drugs through the highly absorptive lining of the mouth into the systemic blood circulation. NovaMist™ may provide substantial potential benefits compared to other modes of drug administration including:

- Faster onset of action;
- Lower dose;
- Enhanced patient compliance and convenience;
- Avoiding the need to swallow;
- Allowing medication to be taken without water; and
- Increased bioavailability of drug by avoiding metabolism by liver.

The designation NovaMist™ describes the delivery of liquid formulations of pharmaceutical product to the oral cavity in the form of a mist that covers the oral mucosal membranes. The oral mucosa is richly supplied with blood vessels and the mucosal membrane is relatively permeable. As a result, contact with these surfaces enables rapid drug absorption into the systemic circulation.

NovaMist™ formulations reach the systemic circulation through different sites within the oral mucosal cavity:

- Sublingual (through the mucosal membranes lining the floor of the mouth);
- Buccal (via the mucosal membranes lining the cheeks); and
- Gingival (via the hard palate and especially through the junction between the gums and teeth).

There are many potential advantages to using NovaMist™, the most important of which is the rapid achievement of therapeutic levels of a desired drug. This method of delivery provides direct access to the systemic circulation, bypassing the harsh environment of the stomach and avoiding the extensive metabolism associated with the first circulatory pass through the liver. Drug delivery via the oral mucosa can also minimize dose variation related to gastrointestinal tract motility, stomach emptying time, food effects, tablet/capsule disintegration and dissolution and enzymatic or chemical degradation in the gut. Due to decreased degradation and higher absorption, oral sprays often permit the use of a lower dose of the active ingredient compared with tablet formulations of the same drug potentially reducing the risk of adverse drug reactions. In many cases, including treatments for patients with difficulty swallowing or nausea, oral spray administration provides enhanced convenience resulting in greater compliance.