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ASX Release

Product Development Market Update

Key points:

- 505(b)(2) abbreviated pathway requires significantly less time and lower investments in direct research and development expenditures
- SUDA prioritising its internal development efforts on 2 projects
- Successful co-development strategy
- Co-development projects de-risks the company and are non-balance sheet dilutive.
- Number of deals that SUDA has transacted on totals 11.

PERTH, AUSTRALIA – 13th May 2019: The Board and Management of Suda Pharmaceuticals Ltd (SUDA) are dedicated to creating a successful pharmaceutical company that specialises in the development of pharmaceutical products utilising our proprietary Oral Spray technology. The Company's focus is on re-formulating existing products, utilising the regulatory and development advantages of USFDA 505(b)2 and EMEA Chapter 10(3) to achieve significant patient benefits and ultimately shareholder returns.

Regulatory Background

Generally, drug development in the U.S. and most countries throughout the world can be an expensive and a long-term process. As an example, the FDA approval processes relating to new drugs may differ depending on the nature of the particular drug for which approval is sought. With regards to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit a full and detailed New Drug Application, or NDA, which includes complete reports of pre-clinical, clinical and laboratory studies to prove such product's safety and efficacy. Prior to submission of the NDA, it is necessary to submit an Investigational New Drug, or IND, to obtain permission to begin clinical testing of the new drug.

Given that SUDA's focus is based on applying its unique spray technology platform (OroMist) to existing drugs that have already been approved and shown to be safe and effective, we are eligible to submit what is known as an abbreviated drug approval package, known as a 505(b)(2) NDA.

The 505(b)(2) application allows SUDA to leverage off the innovator's drug approval data especially with regard to the safety of the drug product. This means that SUDA are not required to carry out the extensive pre-clinical testing that includes animal studies for safety and toxicity. Further, in most cases we are only required to show that drug delivery via our OroMist technology provides the same amount of drug to the blood stream that the innovator was able to achieve (tablet ingestion).

Based on this abbreviated pathway the development of new formulations of our pharmaceutical product candidates, including formulation, testing and submission of an NDA, will require significantly less time and lower investments in direct research and development expenditures than is the case for the discovery and development of new chemical entities. Additionally, by pairing a 505(b)(2) drug with our OroMist technology, we may be able to create additional patent protection, which is obviously of tremendous importance to our partners.

Most importantly, in most cases we able to achieve significant patient advantages such as faster onset with a lower dosage required, resulting in reduced side effects. We can also overcome problems seen with other delivery routes such as gastro intestinal irritation and difficulties in swallowing.

Portfolio Update

SUDA has a broad portfolio of projects at various stages of development. 14 projects are classified as Investigational New Drug Status (IND) and 11 projects with clinical proof of concept or extensive clinical data.

SUDA's board and management acknowledge that the Company needs to focus on delivering a select number of key projects and to deliver shareholder return. As a result, SUDA is actively developing Anagrelide and Midazolam oral sprays for the market. The board believes these drugs, due to their market size and unique attributes which make them ideal candidates for re-formulation, can deliver substantial long term returns to shareholders.

Outside these two priority drugs, we are actively carrying out work on fully funded co-development projects for partners on Sumatriptan and Cannabinoids, and we are carrying out funded contract work on existing contracts around the ZolpiMist project.

All other projects are on hold and will only be continued with third party funding through partnerships (co-development or feasibility studies). The board believes that this will provide the best return for our shareholders.

Table 1: example of projects that SUDA has data on.

(Note: for those compounds in **purple** SUDA has clinical Proof of Concept data)

Analgesics	Local anaesthetics	Anxiolytics	Anti-emetics	Anti-migraine
Afentanyl	Bupivacaine	Buspirone	Aprepitant	Almotriptan
Baclofen	Levobupivacaine	Clorazepate	Casopitant	Eletriptan
Butorfanol	Lidocaine	Diazepam	Dolasetron	Frovatriptan
Codeine	Mepivacaine	**Midazolam**	Granisetron	Naratriptan
Fentanyl	Prilocaine	Pagoclone	**Ondansetron**	Rizatriptan
Meperidine	Ropivacaine		Palonosetron	**Sumatriptan**
Oxymorphone				Zolmitriptan
Oxycodone				
Sufentanil				
Tramadol				

Anti-inflammatories	Muscle relaxants	Sleep-inducers	Men's & Women's health	Anti-allergy
Dexamethasone	Baclofen	Eszoplicone	**Sildenafil citrate**	**Clemastine**
Hydrocortisone	Carisoprodol	Zalepton	Tadalafil	**Loratadine**
Mesalamine	Dantrolene	Zoplicone	Testosterone	
Montelukast	Metaxalone	**Zolpidem tartrate**	Progesterone	
Olsalazine	**Tizianidine**		**Estradiol**	
Prednosone				
Salsalate				

Project Updates

Sumatriptan Oral Spray (SUD001/SUD019)

Migraine is the third most common disease in the world affecting approximately 15% of the world's population. Migraine is more prevalent than diabetes, epilepsy and asthma combined. Chronic migraine affects approximately 2% of the world's population and migraine affects three-times as many women as men, with this higher rate being most likely hormonally-driven.

Sumatriptan is one of the class of drugs called Triptans which are the world's most commonly used prescription medication for the treatment of migraines.

SUDA has developed a Sumatriptan medication (SUD001) that has been shown to be more clinically effective than tablets with a 40 mg spray at least equivalent to a 100mg tablet but with a faster onset of action.

SUDA has entered into a fully funded agreement with Strides (India) to develop a 2nd generation sumatriptan spray (SUD019) utilising our Hydrotrope technology for the US market (refer to announcement of 8 November 2018). The project is progressing well and is on track with the work plan that was agreed with Strides.

SUDA has progressed discussions with a number of companies for a sumatriptan spray in Latin America and Europe.

Ondansetron (SUD002)

Ondansetron, marketed under the GSK brand name Zofran®, is a medication used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy, or surgery. It is also useful in gastroenteritis. Historically, it is given by mouth or by injection into a muscle or into a vein.

SUDA has developed an oral spray that has been shown in multiple clinical trials to be equivalent to Zofran. The project was originally developed by Novadel Inc. and an NDA was lodged but withdrawn without prejudice due to a potential stability concern. SUDA has investigated the concern and believes that it has overcome the stability issue that was observed.

The project requires further expenditure to perform additional stability studies. SUDA is looking for a partner to fund these studies. SUDA has a number of discussions underway with potential partners.

Sildenafil (Viagra) for erectile dysfunction (ED) (SUD003) and Pulmonary Arterial Hypertension (PAH) (SUD004)

Sildenafil, sold as the brand names Viagra® for ED and Revatio® for PAH, among others, is a medication used to treat erectile dysfunction and pulmonary arterial hypertension. It is taken by mouth or injection into a vein. SUDA has developed an oral spray that has shown, in preliminary clinical trials, to have a slightly faster onset of action and requires slightly less drug to show the same drug levels in the blood. We have stable formulations and we have developed 2 families of patents covering both ED and PAH as well as ED caused by the use of anti-depressants. These patents have been granted in multiple jurisdictions and are continuing to be rolled out. They will remain in force until 2032.

SUDA has a number of active discussions around the project and is actively looking for a partner for our Sildenafil projects to fund the ongoing development of the project.

Midazolam (SUD005)

Midazolam, sold under the brand names Versed® and Buccolam®, is a short acting hypnotic-sedative that is used for anaesthesia, procedural sedation and emergency seizure management (epilepsy). Midazolam is the leading benzodiazepine used for sedation during diagnostic, therapeutic and endoscopic procedures. We believe that SUD005 has the potential to be an easy-to use, rapid onset product useful to relieve the pre-procedure anxiety suffered by many patients prior to undergoing a wide variety of procedures performed in hospitals, imaging centres, ambulatory surgery centres and dental offices.

In the US alone, annually there are approximately 40 million invasive procedures performed in the ambulatory surgical setting, more than 25 million MRI/CT scans and over 90 million paediatric dental procedures performed. Pre- procedure anxiety occurs in approximately 60% of children undergoing surgery and is associated with an increase in post-surgical complications including delirium, pain and sleep disorders, as well as higher levels of use of post-surgical medications. Anxiety interferes with approximately 30% of MRI scans with 5-10% of scans not completed due to anxiety. Pre-procedure anxiety is the number one reason for the use of sedation in dental procedures.

The use of midazolam in the treatment of epilepsy is increasing and there is significant interest from potential partners in both pre-procedural anxiety and in epilepsy.

SUDA has a stable preliminary formulation and is completing development of a clinical formulation utilising the proprietary hydrotrope formulation and expect to be ready for proof of concept (PoC) studies in man by the 1st Quarter 2020.

SUDA is carrying out the development of Midazolam as one of our two key projects. We have strong interest in the product and whilst we are keeping our potential partners informed of our progress we are not considering partnering until we have added value through the PoC study. Once we have PoC data, SUDA's aim is to enter into a fully funded global licensing deal.

SUDA will apply for an ESIC ruling for the project in the 2019/20 financial year.

ArTiMist (SUD006)

SUDA will release a more detailed update on ArTiMist once we have received and taken advice on the final Delegates' letter. This letter is expected this month.

ZolpiMist (SUD014)

Zolpidem tartrate is the active ingredient in Ambien®/Stilnox®/Stilnoct®, a leading hypnotic/sleep induction agent marketed by Sanofi-Aventis. SUDA holds a license for the world-wide rights (except North America and Canada) from Aytu Bioscience in the US.

SUDA's directors and management are buoyed by the strong interest in ZolpiMist and by its potential to be a significant value generator. The Company is striving to create ZolpiMist into a future long-term recurring revenue stream.

In June 2018, SUDA announced that Magna Pharmaceuticals, the NDA holder for ZolpiMist and SUDA's Licensor, had transferred their rights to ZolpiMist to Colorado company Aytu Biosciences a specialty pharmaceutical company focused on commercialising novel products that addresses significant patient needs. Aytu's strategy is to continue building its portfolio of revenue-generating

products, leveraging its focused commercial team and expertise to build leading brands within large therapeutic markets. For more information on Aytu visit their website at /aytubio.com.

The Aytu-Suda licensing agreement calls for SUDA to lead commercial development and sublicensing efforts for ZolpiMist in major territories outside the United States and Canada, including Europe, Asia, and Latin America. The global sleep aid market is estimated at almost $50 billion in annual revenue and is estimated to reach nearly $80 billion in 2022.

SUDA has already signed sublicensing agreements in key markets with large, multi-national pharmaceutical companies and has agreements in place in China, Chile, Brazil, Mexico, and throughout South East Asia. Additional sublicensing discussions are ongoing with additional prospective sublicensees.

The first ZolpiMist licensing agreement was signed with Chinese pharmaceutical company Eddingpharm (EDP) for the exclusive sale and distribution of ZolpiMist in mainland China. Due to delays in the regulatory process SUDA has entered into discussions to terminate the agreement with EDP.

Since SUDA and EDP originally entered into the agreement, there has been a number of positive changes to the Chinese regulatory process. In discussions with various parties we understand that the changes that have been introduced will have the potential to shorten the path to market for drugs that are approved by external regulatory agencies and will potentially reduce the need for further clinical studies in China.

SUDA is in discussions with other companies in China to license ZolpiMist into the region.

The second agreement is with Teva Pharmaceuticals for Brazil, Chile and Mexico. Teva has already lodged its marketing approval in Chile and is working closely with the SUDA team to progress the application in the large market of Brazil. Teva is continuing to evaluate the Mexican market. Marketing approval is the final stage before SUDA is able to achieve further milestones and the commencement of royalties.

Based on a study to assess sleep disorders in the adult population of four large metropolitan areas in Teva's licensed territory, the prevalence of insomnia, was estimated to be 35%, with 15% of the surveyed subjects taking sedatives. This is a higher prevalence than in most other parts of the world.

Our third deal was signed in late December 2018 with Mitsubishi Tanabe Pharma Singapore Pte Ltd (MTPS), a wholly owned subsidiary of Mitsubishi Tanabe Pharma Corporation. The Agreement is for an exclusive licence for, and supply of, ZolpiMist for the Philippines, Malaysia and Singapore and options for Thailand, Indonesia, Vietnam, Myanmar, Cambodia, Laos and Brunei. The option period is for 12 months.

Further to these deals, SUDA has received considerable interest in ZolpiMist from companies ranging from multinationals to specialised pharmaceutical companies covering diverse territories.

SUDA is able to provide a breakdown of developments with ZolpiMist by region:

1. ASEAN/Asia: Further discussions with companies interested in Japan; South Korea and a number of other Asian countries.
2. MENA (Middle East and North Africa): discussions in various stages with companies for the full MENA region as well as specific talks for the United Arab Emirates and Kuwait.
3. South America: agreement signed with Teva for Brazil, Chile and Mexico; advanced negotiations for other countries in the region including Argentina, Peru, Ecuador, Columbia, Uruguay, Bolivia, Central America, Dominican Republic, Paraguay and Venezuela.
4. Europe: advanced negotiations with pharma companies for Spain, Italy, France and

Germany.

5. Eastern Europe: specific talks for the regions of Turkey and Russia.

In Australia, SUDA has lodged its Marketing Application with the Australian Therapeutic Goods Administration for the approval of ZolpiMist in the Australian market. SUDA is now looking for a partner for the Australian market.

SUDA's current agreements and all negotiations are based on SUDA's standard business model where SUDA will supply the product and receive an upfront payment followed by payments for achieving regulatory and sales milestones. Further to these payments, SUDA will receive a handling fee as well as double digit royalties on sales (current 10-year forecast (after approvals) on signed deals is approximately US$60Mn as previously reported). Furthermore, based on the current agreements only, SUDA has already received US$0.8Mn in upfront fees and will potentially receive a further US$2.1Mn (approx. A$2.8Mn) in milestone payments.

Anagrelide (SUD018)

SUDA will provide a detailed update on the anagrelide project to the market in the next few weeks (refer to announcement of 21 February 2019 for background information).

Anagrelide hydrochloride (Agrylin®, Xagrid®) is an orally administered drug which selectively reduces platelet count in humans and is used for such purposes in the treatment of myeloproliferative diseases (MPDs), such as essential thrombocythemia (ET), where an elevated platelet count may put the patient at increased thrombotic risk. Anagrelide has been on the US and European markets for some 19 years. As a consequence, its clinical safety profile is well defined. Furthermore, as a small molecule, it is relatively cheap to make and is now out of patent or other forms of protection. SUDA has a patent application currently in National Phase for the use of anagrelide in the treatment of Cancer.

There is now extensive clinical evidence highlighting the presence of thrombocytosis in many different cancers and the role that excessive numbers of platelets play in promoting cancer cell growth, tumour establishment including angiogenesis and subsequent metastasis, particularly potentially fatal bone metastases. Paraneoplastic thrombocytosis is observed in some 10-57% of patients with cancer with the number varying depending on cancer cell type and disease stage. Since cancer cells stimulate megakaryocytopoiesis / platelet production which in turn drives cancer cell growth, this leads to a vicious cycle or pathogenic loop being established.

The role of platelets in cancer progression is now becoming better understood. With increased platelet count equating to poor clinical outcomes whilst it has been shown that reducing platelet counts results in improved clinical outcomes.

SUDA's newly formulated anagrelide oral spray will represent a radical new approach to the treatment of cancer which will be applicable across a wide range of solid tumours. Newer cancer treatments involve immunotherapy which stimulate the patient's own immune system. Anagrelide would be complementary to such treatments rendering circulating cancer cells more susceptible to attack by the body's own "killer" cells and could thus offer a novel and valuable new neoadjuvant or adjuvant therapy. It also represents a "first in class" for this new treatment strategy for cancer.

SUDA's scientists have made a number of significant breakthroughs in the development of an oral spray formulation and we are well progressed along the formulation pathway. We believe that the work carried out by the SUDA scientists will allow us to increase the patent coverage for SUDA around this project.

Cannabinoids (SUD020)

SUDA has entered into a fully funded agreement with Australian cannabis company Zelda Therapeutics (Zelda) to develop various cannabis based oral sprays for use in a number of

therapeutic indications. Zelda has been formed to bring together some of the world's leading researchers and clinicians to address unmet needs for clinical validation of medicinal cannabis to treat a variety of ailments.

SUDA has now all the appropriate licenses to import, warehouse and carry out research and development on all forms of medicinal cannabis. Further to this, SUDA is able to manufacture product for use in pre-clinical and phase I clinical trials. This legal infrastructure provides SUDA and our partner a significant advantage in managing the development of new cannabis oral sprays.

As SUDA has now a full suite of license and permits to allow the company to carry out cannabis research, we are also working with Zelda to provide other pharmaceutical services to facilitate the ongoing development of Zelda's products.

Co-Development Projects

A key part of the SUDA business strategy is to work with partners in developing specific products for the partner using out technology platform and knowhow.

We have been successful in this process with the current Strides and Zelda projects and the previous option and feasibility agreement with Pfizer. Andrew Curtis and David Phillips are focused on finding partners that can add significant value to SUDA through co-development programs. We are presently in discussions (both advanced and early) with a number of global top 20 pharmaceutical and large specialty Pharmaceutical companies on the co-development of their own or specialty generic products. SUDA is buoyed by the high level of interest and status of our negotiations in this area.

Furthermore, co-development projects also provide a number of intangible benefits to the Company through extension of our internal know-how and intellectual property, funding of further operational assets, expansion of our human capital and human intellectual property whilst co-development deals can assist in de-risking the company, as often these deals are non-balance sheet dilutive.

Business Development

SUDA has completed three commercial transactions* this financial year.

Table 2: Out Licensing Business Development deals and key payments currently in place.

Company	Product	Type of Deal	Upfronts/Milestones ($)	Royalties	Comments
Strides*	Sumatriptan	Development and Supply	US$400,000 upfront Up to US$600,000 in milestones	Yes	Fully Funded Development program
Zelda*	Cannabinoids	Option and Feasibility	AU$200,000	N/A	Fully Funded Development Program
Mitsubishi Tanabe*	ZolpiMist	License and Supply	US$100,000 Upfront Up to US$880,000 in milestones	Yes	
Teva	ZolpiMist	License and Supply	US$300,000 Upfront Up to US$1,750,000 in Milestones	Yes	
Eddingpharm	ZolpiMist	License and Supply	US$ 300,000 Upfront US$ 200,000 in Milestones	Yes	
Pfizer	Not Stated	Option and Feasibility	Not Stated	N/A	Option expired
Kwang Dong**	Ondansetron	License	US$100,000 Upfront US$200,000 in Milestones	Yes	Initial payment received by Novadel

** Carried from Novadel but re-confirmed by SUDA

Table 3: In licensing/Asset Purchase deals

Company	Product	Type of Deal	Territory
Magna Pharmaceuticals/ Aytu BioScience	Zolpimist	In-License	World Wide except USA and Canada
Aluztra	Anagrelide	Asset Purchase	Global
Novadel	Various	Asset Purchase	Global
London Pharma	ArTiMist	Asset Purchase	Global

This brings the number of deals that we have transacted to 11.

The board is confident that this number will continue to grow, with a combination of small regional and global licensing deals.

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NOTES TO EDITORS:

About SUDA Pharmaceuticals Ltd

SUDA Pharmaceuticals Ltd (ASX: SUD) is a drug delivery company focused on oro-mucosal administration, headquartered in Perth, Western Australia. The Company is developing low-risk oral sprays using its OroMist® technology to reformulate existing pharmaceuticals. The many potential benefits of administering drugs through the oral mucosa (i.e.: cheeks, tongue, gums and palate) include ease of use, lower dosage, reduced side effects and faster response time. SUDA's product pipeline includes ZolpiMist™, a first-in-class oral spray of zolpidem for insomnia. ZolpiMist is marketed in the USA and SUDA has rights to the product outside of the US and Canada. Other products in development include oral sprays for the treatment of: migraine headache, chemotherapy-induced nausea and vomiting, erectile dysfunction, PAH, epileptic seizures and pre-procedural anxiety and cancer. For more information, visit www.sudapharma.com

This announcement contains certain statements which may constitute forward-looking statements or information (''forward-looking statements"), including statements regarding negotiations with third parties and regulatory approvals. These forward-looking statements are based on certain key expectations and assumptions, including assumptions regarding actions of third parties and financial terms. These factors and assumptions are based upon currently available information and the forward-looking statements contained herein speak only as of the date hereof. Although the expectations and assumptions reflected in the forward-looking statements are reasonable in the view of the Company's directors and management, reliance should not be placed on such statements as there is no assurance that they will prove correct. This is because forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could influence actual results or events and cause actual results or events to differ materially from those stated, anticipated or implied in the forward-looking statements. These risks include, but are not limited to: uncertainties and other factors that are beyond the control of the Company; global economic conditions; risk associated with foreign currencies; and risk associated with securities market volatility. The Company assumes no obligation to update any forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements, except as required by Australian securities laws and ASX Listing Rules.