

ASX Release

Corporate Presentation

PERTH, AUSTRALIA – 27 August 2019: SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery (“SUDA”), today announces that Mr Stephen Carter and Mr David Phillips are presenting to brokers and investors in Sydney and Melbourne this week.

A copy of the Corporate Presentation follows.



Further information:

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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

SUDA
PHARMACEUTICALS LTD

Faster, safer, oro-mucosal
spray delivery for
ex-blockbuster drugs



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Company Highlights

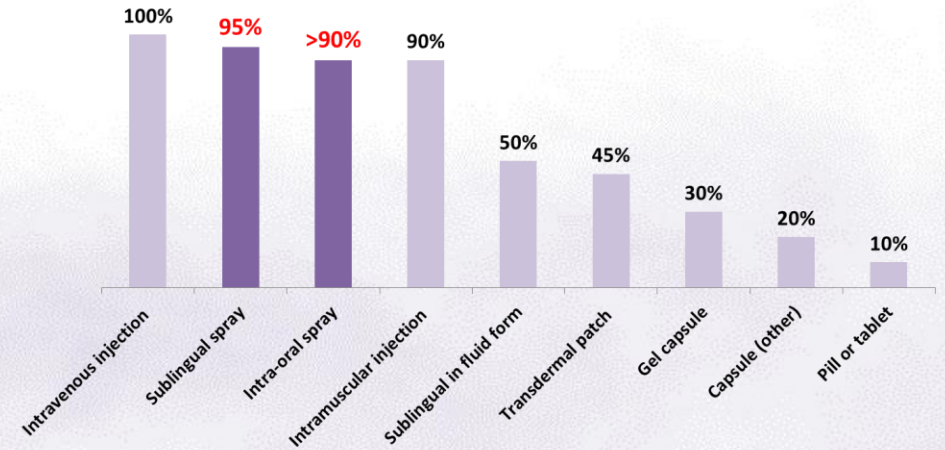
- Unique platform technology for reformulating existing billion-dollar drugs for oral delivery
- Faster onset, potentially smaller doses & safer delivery for ex-blockbuster drugs
- Large target markets including patients suffering migraine, anxiety, erectile dysfunction, nausea and cancer
- Reformulation into an oral spray offers fast approval & significantly lower cost under the FDA'S accelerated 505 (b)(2) pathway to approval
- Promising opportunity to take a drug approved for blood disorder & convert it to an oro-mucosal spray cancer drug
- Technology validated with licensing deals completed with Teva and Mitsubishi
- Robust intellectual property portfolio with over 50 patents
- Experienced leadership team with modest operating overheads
- Attractive valuation with near-term value enhancing events



Unique advantages of SUDA's spray delivery

- The drug is **ABSORBED DIRECTLY INTO THE BLOODSTREAM THROUGH THE MUCOSA**
- This presents significant and unique benefits and advantages:
 - **LESS DRUG IS REQUIRED** - direct absorption avoids hepatic first-pass effect which means less drug needs to be metabolized.
 - **FASTER ONSET OF ACTION** – time at which drug becomes effective is significantly reduced.
 - **REDUCTION IN DOSE** due to increased bioavailability as drug is absorbed directly into the bloodstream.
 - **LESS ADVERSE SIDE EFFECTS** – reduction in dose means **reduction in adverse side effects**
 - **REDUCES** plasma level variability for drugs with **food effect**
 - **AVOIDS GASTRO-INTESTINAL SIDE EFFECTS**
 - **GREATER TOLERABILITY** in patients with nausea and vomiting
 - **Can be administered to unconscious and uncooperative patients**
 - **HIGH PATIENT COMPLIANCE** due to elimination of injection pain or the need to swallow^{1,2} or inhale

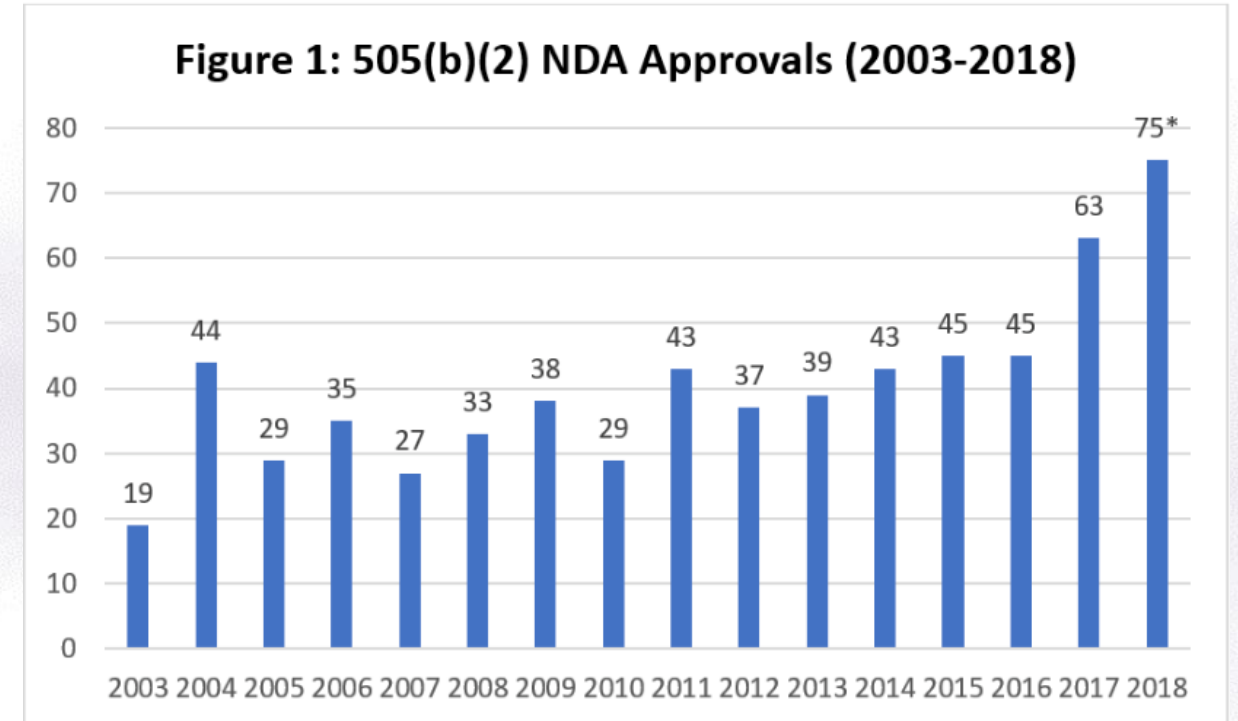
1. >40% of adults experience difficulties swallowing
2. >50% of children (6 to 11 years) have problems swallowing tablets



What Is The FDA 505 (b)(2) Approval Pathway?

- Under a 505(b)(2) submission the FDA allows a company to rely on data such as safety & efficacy about a previously approved drug, not developed by the company
- In simple terms this means SUDA can rely on clinical data or literature produced by other companies, to get their oro-mucosal sprays approved
- This can result in much less expensive and much faster, route to market
- Europe has a similar program under the EMEA Chapter 10(3) legislation

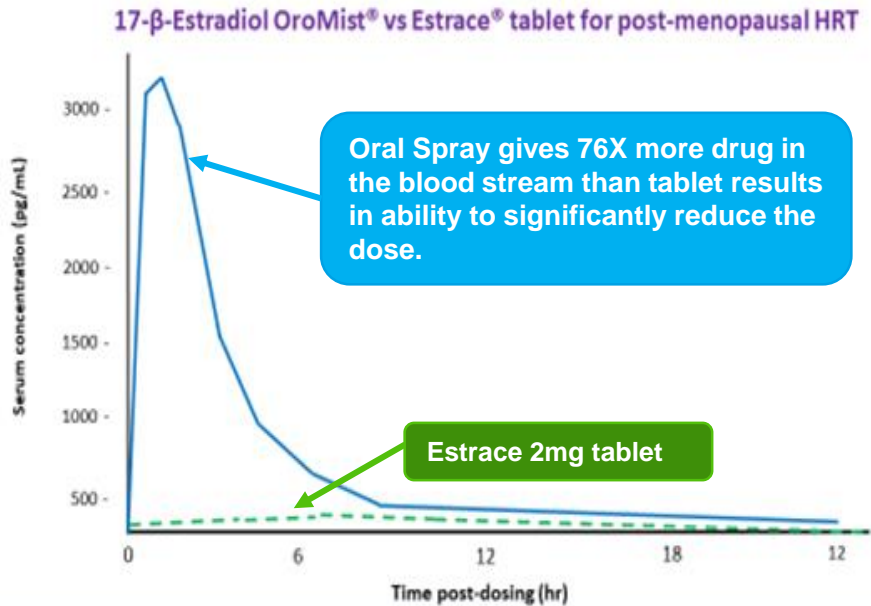
The number of 505(b)(2) approvals increased 19% from [63 in 2017](#) to a record-breaking 75 in 2018.



Oro-mucosal Spray Delivery | Unique Advantages

Enhanced Bioavailability

Clinical Data | Enhanced Bioavailability

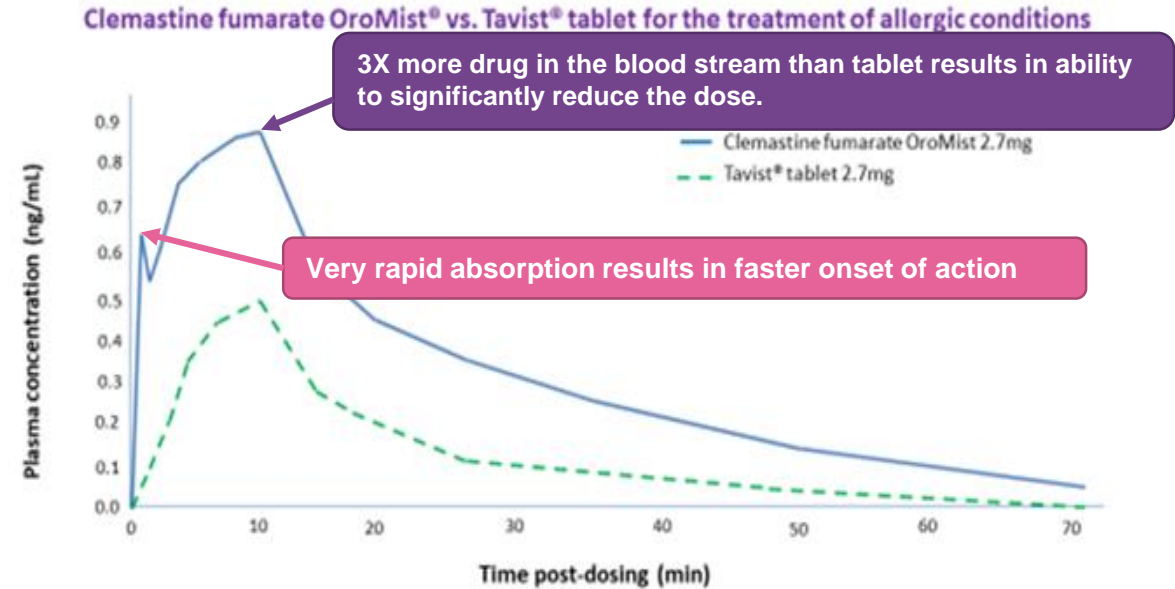


Estradiol OroMist® achieved estradiol blood levels faster than Estrace® tablet
 AUC was 10x higher and C_{max} 76x greater
 T_{max} for OroMist® was 42min vs 8.3hr for Estrace® tablet

Source: Estradiol OroMist pilot PK study in post-menopausal women

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Clinical Data | Enhanced Bioavailability



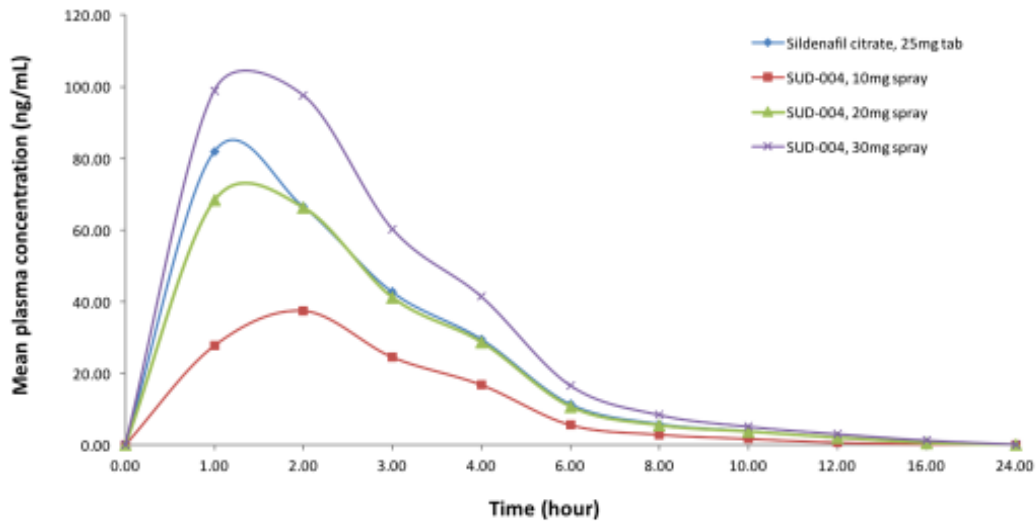
Clemastine fumarate 2.7mg OroMist® blood levels were 3x higher when compared to Tavist® 2.7mg tablet and therapeutic levels were reached in 5-7min with OroMist® vs. 25-30min for the tablet. Sedating effects with OroMist® were NO greater than the tablet

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Oro-mucosal Spray Delivery | Unique Advantages

Clinical Data | Linear Dose Response

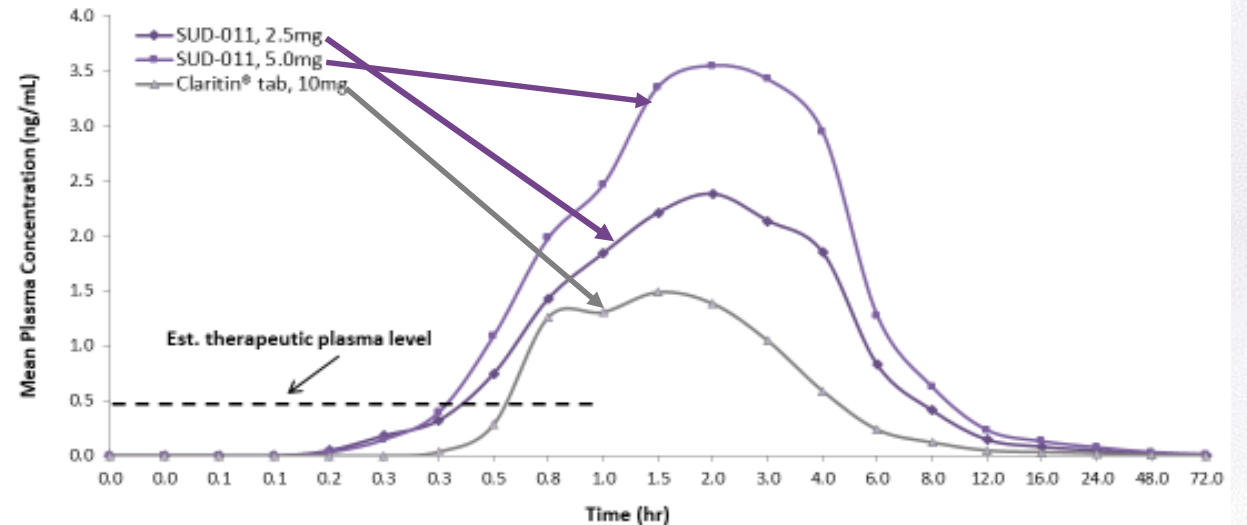
Sildenafil OroMist® (SUD-003) vs. Viagra® 25mg tablet for the treatment of ED



Sildenafil OroMist® (SUD-003) dose adjusted 10, 20 and 30mg PK curves confirm that OroMist provides a linear dose response

Clinical Data | Enhanced Bioavailability

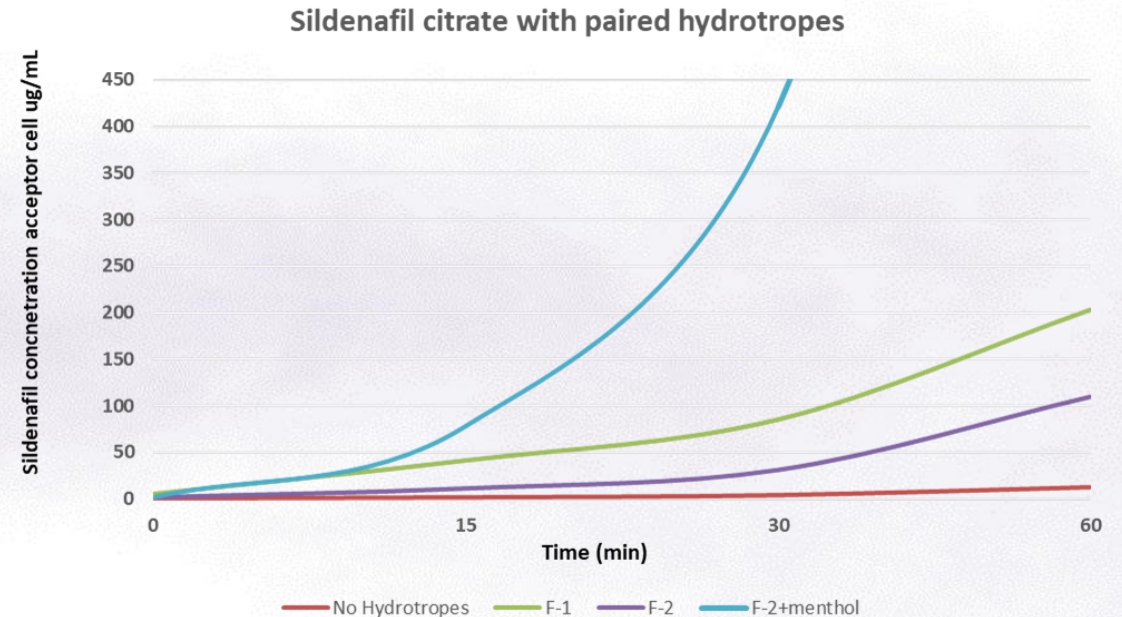
Loratadine OroMist® (SUD-011) vs. Claritin® tablet for the treatment of allergic conditions



Loratadine OroMist (SUD-011) 2.5mg and 5mg achieved therapeutic plasma levels earlier and maintained for longer than Claritin® 10mg tab using less API

SUDA's Proprietary Hydrotrope Technology

- Suda's Hydrotrope technology offers significant benefits for drug delivery; Improve drug transport speed across mucosa
 - Assists to overcome issues around drug entry and exit from mucosa
 - Enhanced bioavailability
 - Less drug required
 - Better side effect profile
- Suda has Intellectual property around the technology
 - Mucosal Active Agent Delivery
- Hydrotropes are Generally Regarded As Safe (GRAS) compounds or on the Inactive Ingredients Database (IID)



Significant increase in absorption with SUD-003 plus hydrotropes vs. base formulation of SUD-003 at 15-minute time point in *ex-vivo* buccal membrane model

GMP Manufacturing | Ease of Manufacture & Low COGS

- SUDA holds a licence to manufacture therapeutic goods from the Australian TGA. Licence number MI-2017-LI-13480-1
- SUDA is accredited to ISO9001:2015
- SUDA is an Australian Government Registered Research Provider and
- SUDA's approved manufacturers provide a global manufacturing solution for our partners



SUDA Transactions With Major Pharma's Validate Our IP...



Mitsubishi Tanabe Pharma



Strides



Consumer Healthcare



AYTU
BioScience



EDDING 亿
PHARM 腾

MAGNA
Pharmaceuticals, Inc.



zelda
THERAPEUTICS



Cann Pharmaceutical
Australia



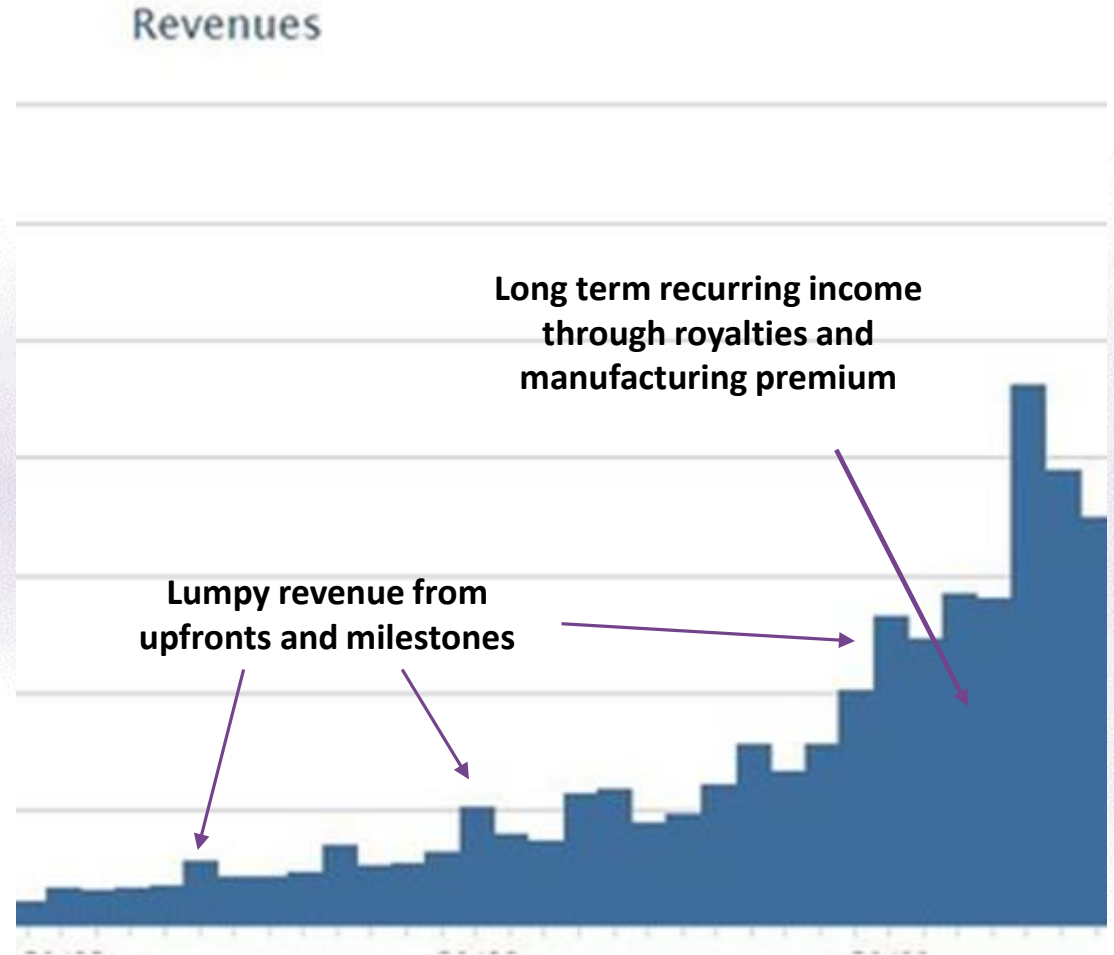
Kwangdong



SUDA
PHARMACEUTICALS LTD

Business Model and Revenue

- Focused on upfront Cash with Milestones at key development goals and a longer term focus on recurring revenue.
- Short to Medium term smaller deals longer term larger deals with Mid to large Pharma around platform opportunities and key internal projects.
- Fully funded co-development deals
- Achievable Milestones
- Premium on manufacturing can match or exceed the royalty
- Royalty's can change the long-term financial profile of the company



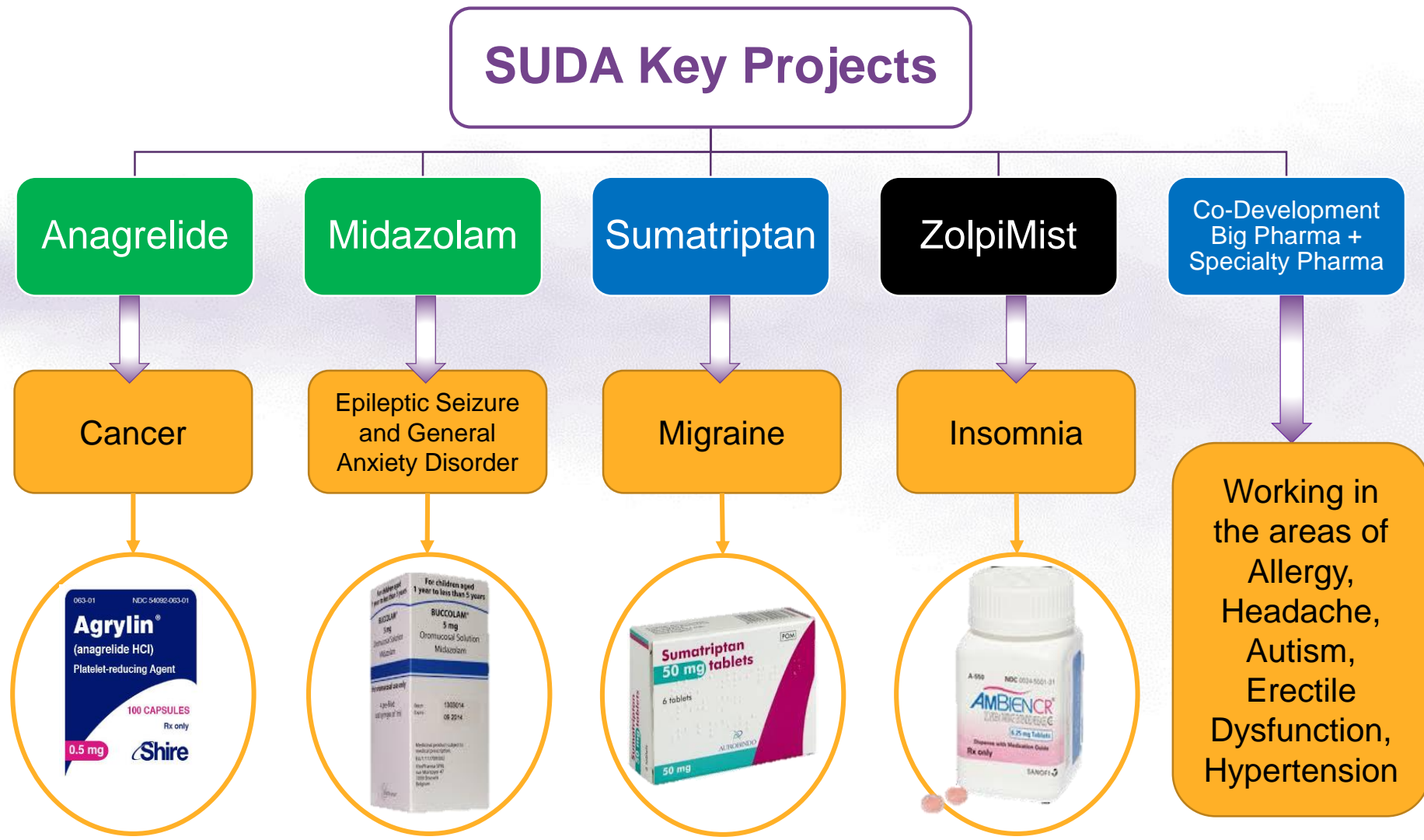
US BD Emphasis: Deal Flow, Building Sustainable Business Model:

- **Big Pharma-** Longer “selling” cycle... internal Business/Scientific Champion
 - Established Products, bridge to Branded Products
 - Consumer/OTC
 - Animal Health
- **Small, Medium-Size Biotech/Pharma- (+\$B)** Shorter selling cycle- focus on deal value, short development/regulatory timelines
 - SOD Generics
- **Strategic Focus**
 - CNS
 - Paediatrics
 - Non-Opioid Pain
 - Animal Health
 - Consumer/OTC
- **Other Activities**
 - Investor Community (PE Opportunities)
 - Patient Advocacy
 - Physician Specialty Organizations
 - Meetings, Conventions, Scientific Symposia



Pharmaceutical Hotspots

Key Projects



Anagrelide 505(b)(2) Route to a Cancer Drug via OroMist

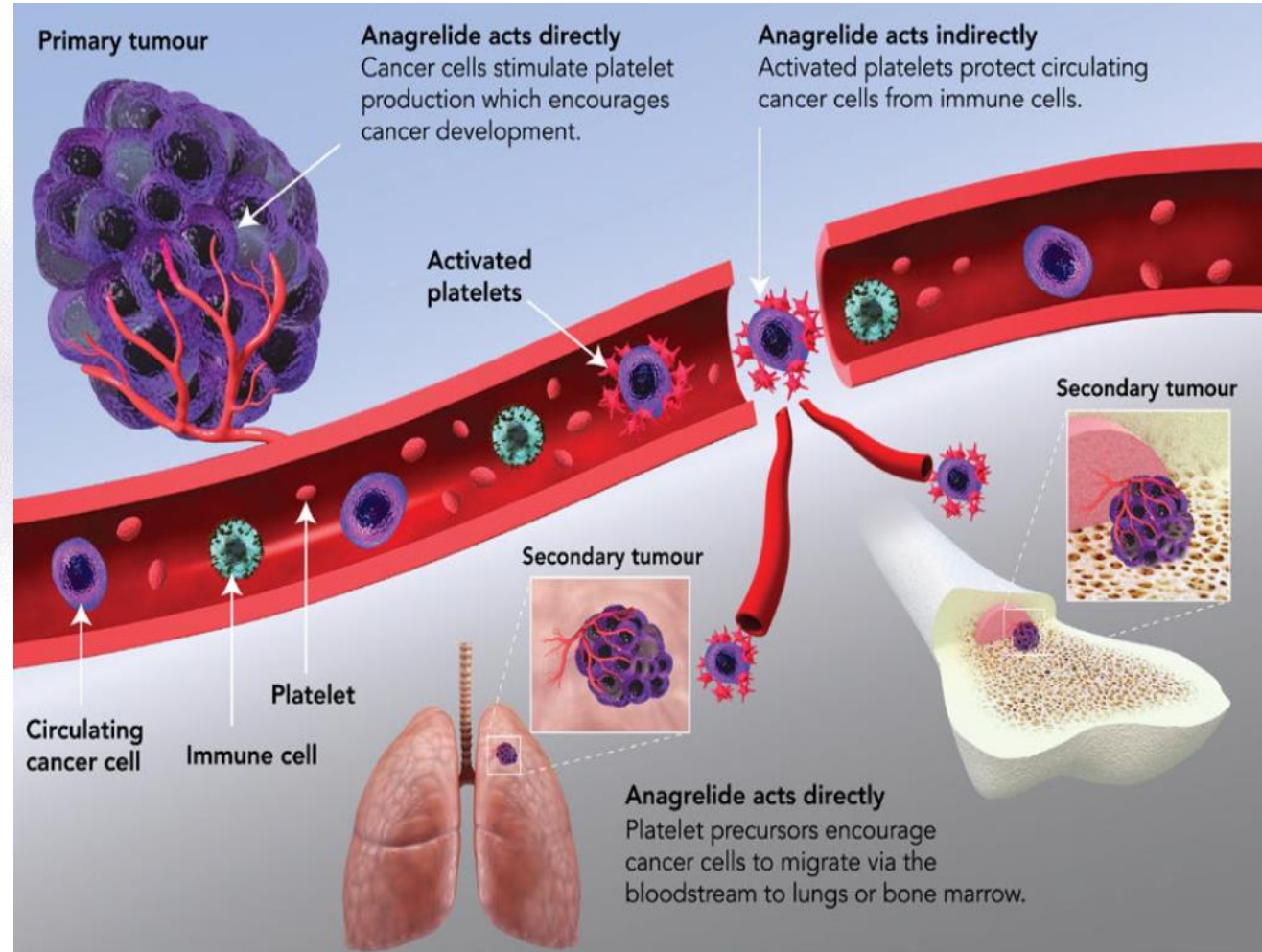


- Anagrelide is an approved generic drug for treating a rare blood disorder where a patient's platelet count is too high
- There is substantial scientific evidence that cancer patients with high platelet counts have a poor prognosis, so a drug which lowers platelet count could play an important role in cancer treatment
- Many aggressive cancers such as ovarian show platelet overproduction
- Anagrelide has cardiac side effects but if delivered via SUDA's oro-mucosal spray this toxicity is potentially avoided
- Reformulation work for an OroMist spray of anagrelide is underway
- A reformulation could be used across a broad spectrum of solid tumors as they have been shown to share a common dependency on high platelet count to help cancers grow
- SUDA owns intellectual property for its use in cancer titled;
 - "Prevention and treatment of metastatic disease in thrombocytotic cancer patients"



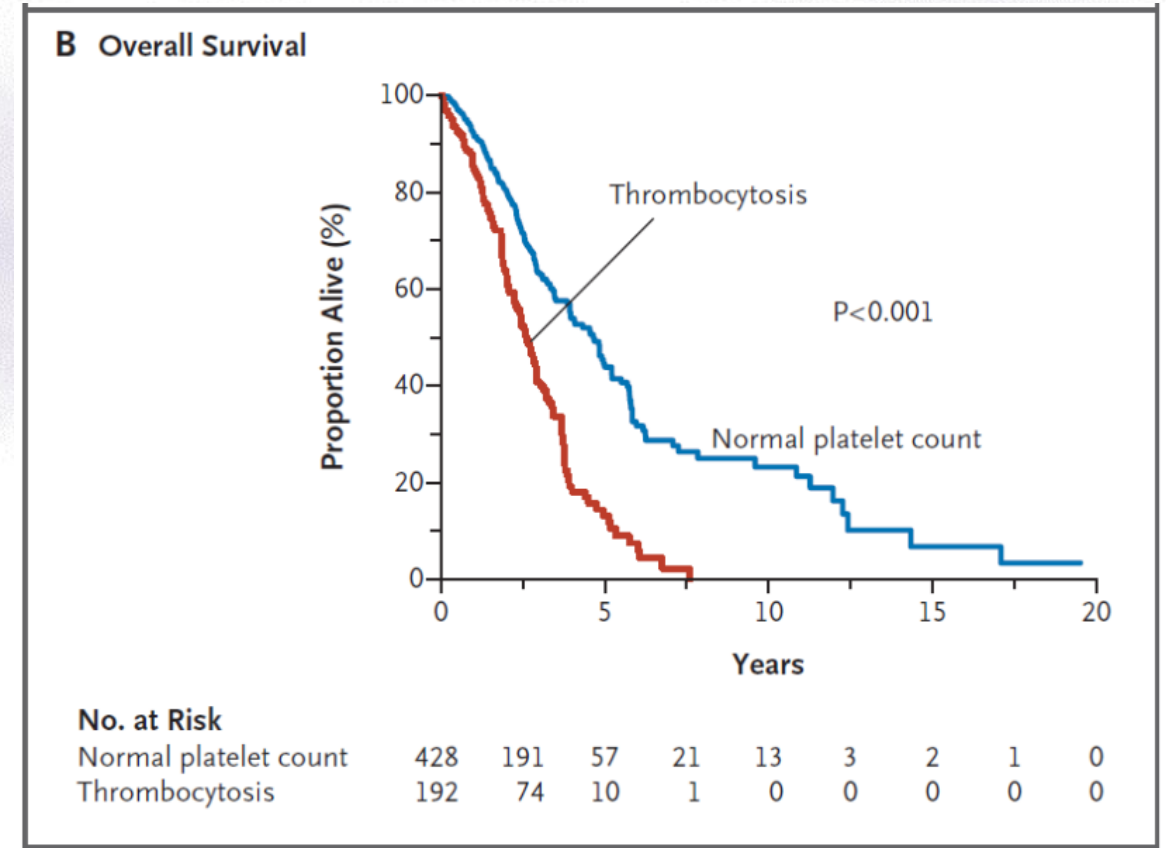
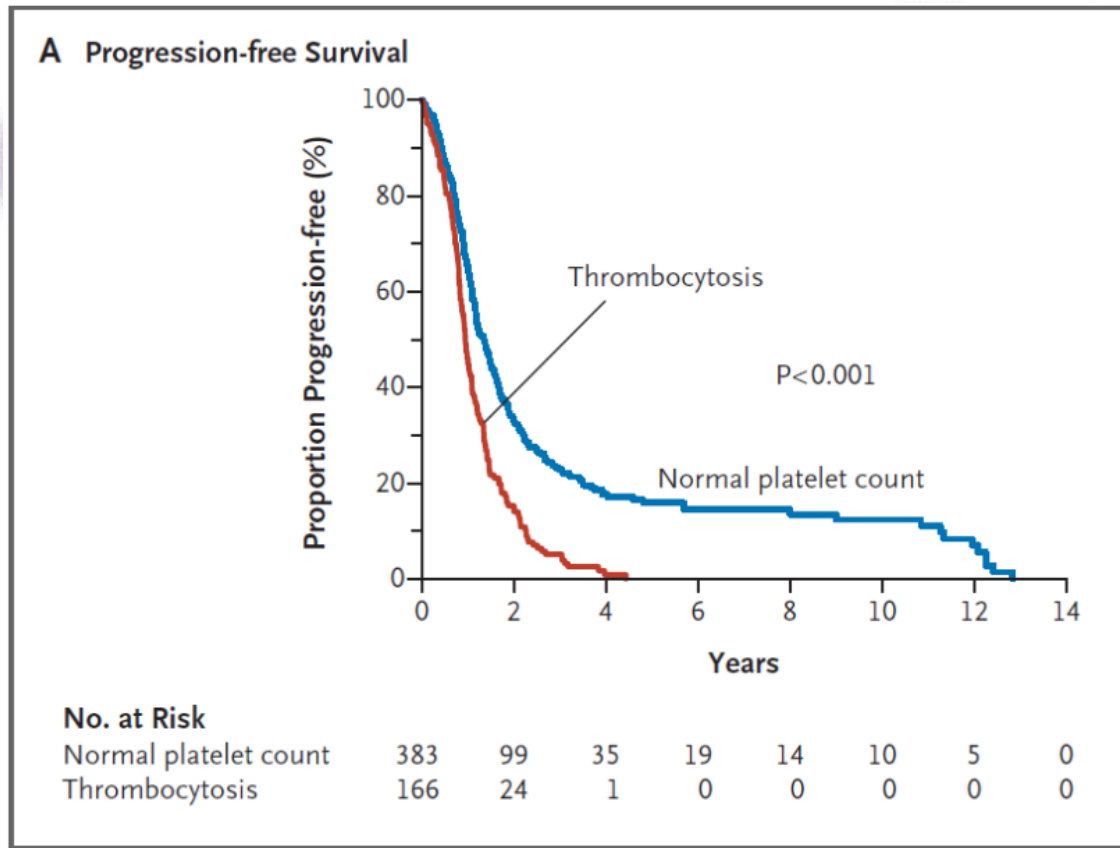
Central role of platelets in cancer

- **Thrombocytosis** is a disorder in which your body produces **too many platelets**.
- A **cancer diagnosis** should be considered in patients with blood test results showing thrombocytosis even if cancer was not initially suspected.
- Platelets are known to become **aberrantly activated** in cancer patients, which leads to **higher risk** of thrombosis and metastasis.
- Further, platelets are involved in:
 - **Tumour angiogenesis**
 - **Lymph-angiogenesis**
 - **Metastatic progression**
 - **Cancer cell proliferation**
 - **Shielding cancer cells from immune attack**
- Reducing Platelet count **reduces tumour burden** and **improves survival**



Importance of High Platelet Count in Cancer

- Paraneoplastic thrombocytosis (PNT) affects 10-57% of patients with solid tumor cancers



Stone et al, 2012 New England Journal of Medicine 366(7): 610-618

High Platelet Count = Reduced Survival

Cancer Type	Incidence (US 2013)		Impact of High Platelet Count (Thrombocytosis)
Breast	232,340	↓	Survival (RR1.7)
Lung	228,190	↓	Survival @5yrs 4% vs 18%
Colorectal	142,820	↓	Survival (RR1.7)
Melanoma	76,690	↓	Survival 3.6 month vs 8.8 month
Kidney	65,150	↓	Survival 92 month vs 151 month
Stomach	21,600	↓	Survival @3 years 23% vs 73%
Mesothelioma	3,500	↓	Survival 6.2 month vs 9.4 month

Anagrelide Cancer Thesis Supported By Leading Peer Review Publications

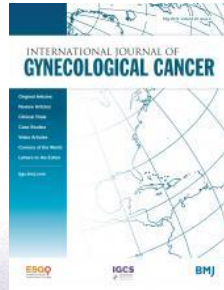
2015



J Gastrointestinal Cancer. 2015 Dec;46(4)

Thrombocytosis and raised CRP levels predicts advanced stage in esophageal carcinoma

2015



Int J Gynecol Cancer. 2015 Nov;25(9)

Prognostic significance of pretreatment thrombocytosis in cervical cancer patients treated with definitive radiotherapy

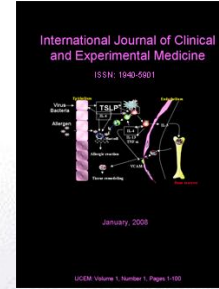
2015



Medicine (Baltimore). 2015 Sep 18; 94(37)

The prognostic value of platelet count in patients with hepatocellular carcinoma: A systematic review and meta-analysis

2015



Int J Clin Exp Med. 2015 Jul 15;8(7)

Platelet to lymphocyte ratio plays an important role in prostate cancer's diagnosis and prognosis

2015



Int J Surg. 2015 Jun;18

Relationship of postoperative thrombocytosis and survival of patients with colorectal cancer

2015



PLoS One. 2015 May 8;10(5)

The association of platelet count with clinicopathological significance and prognosis in renal cell carcinoma: A systematic review and meta-analysis

2015



World J Gastroenterol. 2015 May 7; 21(17)

Prognostic significance of preoperative platelet count in patients with gallbladder cancer

2015



Int J Clin Exp Med. 2015 Apr 15; 8(4)

Prognostic role of elevated platelet count in patients with lung cancer: a systematic review and meta-analysis

2015



Acta Oncol. 2015 Jan 22;54(7)

Paraneoplastic thrombocytosis independently predicts poor prognosis in patients with locally advanced pancreatic cancer

2014



World J Gastrointest Oncol. 2014 Feb 15; 6(2)

Thrombocytosis as a prognostic marker in gastrointestinal cancers

2013



Breast cancer Res. 2013 Jul 31;15(4)

Platelets, coagulation and fibrinolysis in breast cancer progression

2012



J Cancer Res Clin Oncol. 2012 Oct;138(10)

Change in platelet levels during radiotherapy with concurrent and adjuvant temozolomide for the treatment of glioblastoma: A novel prognostic factor for survival

SUDA
PHARMACEUTICALS LTD

Midazolam - Epileptic Seizures & General Anxiety Disorder

- Midazolam was invented by Roche in the mid 70's and approved by the FDA in 1985
- SUDA has developed a Midazolam oro-mucosal spray at two dose levels (2.5mg and 5.0mg) utilising SUDA's permeation-enhancing technology with a pleasant strawberry-mint flavour
- Target indication's are focussed on the two large markets of
 - Emergency treatment/management of epileptic seizures in children
 - General Anxiety Disorder (GAD) including Pre-procedural anxiety in in/out-patient procedures i.e. imaging, medical and dental procedures
- Anticipate 505(b)(2) development path
- Intellectual Property being developed
- Large markets
 - Midazolam and is the most used benzodiazepine in conscious sedation and pre-procedural anxiety.
 - Epilepsy is the 4th most common neurological disorder in the US after migraine, stroke, and Alzheimer's disease (Hirtz et al., 2007)



ArTiMist® | Developed with a Child in Mind

ArTiMist

- **First-in-class** sublingual spray formulation of Artemether for the treatment of severe paediatric *P. falciparum* malaria where IV artesunate is not available.
- **First-in-class** for children with uncomplicated *P. falciparum* malaria who cant reliably take oral medication.

Clinical

- **Positive and strong clinical data** from a multi-country Phase III superiority study of ArTiMist vs. IV quinine in severe paediatric malaria

Regulatory

- Submitted to Therapeutic Goods Administration (TGA), Australia and whilst all sections of the TGA recommended approval the ACM rejected approval.
- Currently under appeal Decision due 2nd October

Intellectual Property (IP)

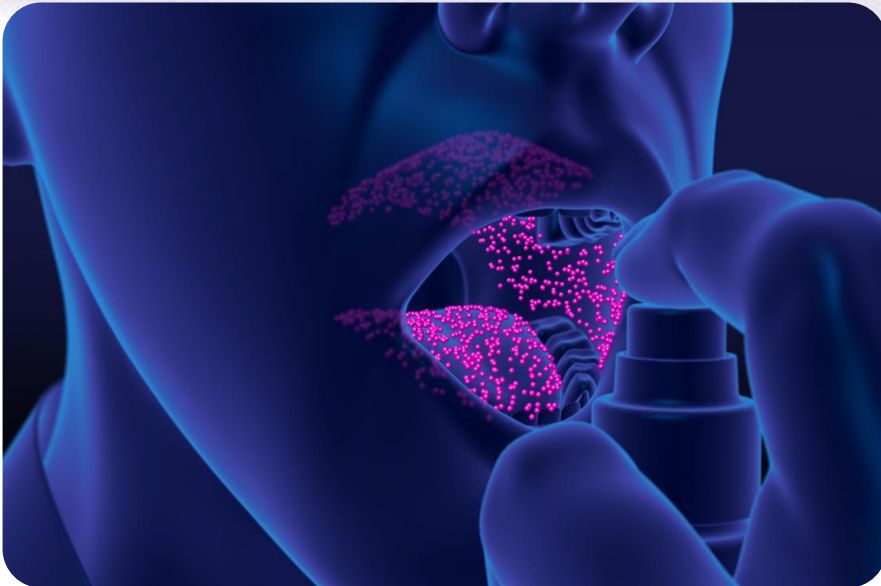
- **Comprehensive IP position** with a significant number of granted patents

Business Development

- **Comprehensive BD outreach** with detailed DD carried out by Sanofi etal. Discussions with Sanofi, Novartis, Apexpharma, Protheragen Awaiting TGA appeal.

Drug Development Partnerships.

We offer added-value development services to companies seeking to formulate APIs into proprietary oro-mucosal sprays with unique advantages



- License agreements with major Pharma to jointly develop our spray
- Suda works with our partners to formulate their ex-blockbuster drugs into our oral spray's
- Full feasibility assessment of API to be formulated into an oral spray
- Access to proprietary *ex-vivo* buccal permeation model
- Track record of generating new IP and/or use SUDA's background IP
- Development fully funded by our partner
- Formulation services for Rx, OTC, veterinary, vitamin and nutraceutical oral sprays



SUDA is a Registered
Research Provider



SUDA
PHARMACEUTICALS LTD

Sumatriptan: Co-Development



- Sumatriptan is the generic name for Glaxo's blockbuster migraine drug known as Imitrex. Similar class drugs were developed by Merck & J&J
- Attractive licensing deal for USA signed with large India pharma company, Strides, who focus on 505(b)(2) submissions
- Fully funded development program including clinical trials underway at cost of >\$4m to be funded by Strides
- IND status with FDA further discussions carried out including Type C meeting in 2016
- New formulation with hydrotropes near complete
- SUDA owns intellectual property covering;
 - Mucosal Active Agent Delivery
- SUDA to supply finished product to Strides

Cannabinoids: Co-Development



- SUDA has been building its infrastructure to carry out research into Medical Marijuana and now holds the following licences, issued either by the Government of Western Australia or the ODC, in relation to its cannabinoid projects:
 - Permit to purchase cannabis and cannabinoids for the purpose of research and education;
 - Wholesale Warehousing licence to allow supply of medicines (including cannabis) for use in clinical trials;
 - Good Manufacturing Practice Licence to allow the production of early stage clinical samples (up to Phase 1) and release for supply
 - Permit to purchase and possess cannabidiol, tetrahydrocannabinols and cannabinoids; and
 - To import and export cannabis and cannabinoid products
- In December 2018, SUDA signed an agreement with Zelda Therapeutics to develop an oral spray of pharmaceutical-grade cannabinoid derivatives.
- In June 2019, SUDA signed a binding term sheet with Cann Pharmaceutical Australia (CPA) to develop and supply an oral spray of pharmaceutical-

Zolpomist - Insomnia

- ZolpiMist is SUDA's spray version of the insomnia drug Ambien
- Ambien was Sanofi's blockbuster insomnia drug
- ZolpiMist spray was approved by the FDA in 2008.
- US and Canadian rights to ZolpiMist are owned by Aytu Bioscience
- SUDA has rest-of-world rights, and has licensed Sth America, including Brazil and Mexico, to the Israeli big pharma, Teva. Mitsubishi Tannabe has licensed the rights to 10 ASEAN Countries. Eddingpharm have licensed the rights for China.
- Forecast royalty streams in excess of \$50million over the first 10 years of sales
- Multiple term sheets for Europe, Asia and LatAM in negotiation.
- SUDA to supply finished product to all parties.



Mitsubishi Tanabe Pharma



Existing OroMist® Spray Formulations

Analgesics

- Afentanyl
- Baclofen
- Butorfanol
- Codeine
- Fentanyl
- Meperidine
- Oxymorphone
- Oxycodone
- Sufentanil
- Tramadol

Local Anaesthetics

- Bupivacaine
- Levobupivacaine
- Lidocaine
- Mepivacaine
- Prilocaine
- Ropivacaine

Anxiolytics

- Buspirone
- Clorazepate
- Diazepam
- Midazolam
- Pagoclone

Anti-emetics

- Aprepitant
- Casopitant
- Dolasetron
- Granisetron
- **Ondansetron**
- Palonosetron

Anti-migraine

- Almotriptan
- Eletriptan
- Frovatriptan
- Naratriptan
- Rizatriptan
- **Sumatriptan**
- Zolmitriptan



Anti-inflammatory

- Dexamethasone
- Hydrocortisone
- Mesalamine
- Montelukast
- Olsalazine
- Prednosone
- Salsalate

Muscle Relaxants

- Baclofen
- Carisoprodol
- Dantrolene
- Metaxalone
- **Tizianidine**

Sleep-inducers

- Eszopiclone
- Zalepton
- Zopiclone
- **Zolpidem tartrate**

Men's & Women's Health

- **Sildenafil citrate**
- Tadalafil
- Testosterone
- Progesterone
- **Estradiol**

Anti-allergy

- **Clemastine**
- **Loratadine**
- Doxylamine
- Diphenhydramine

Denotes clinical data available

Oro-mucosal Delivery | IP & Platform Technology

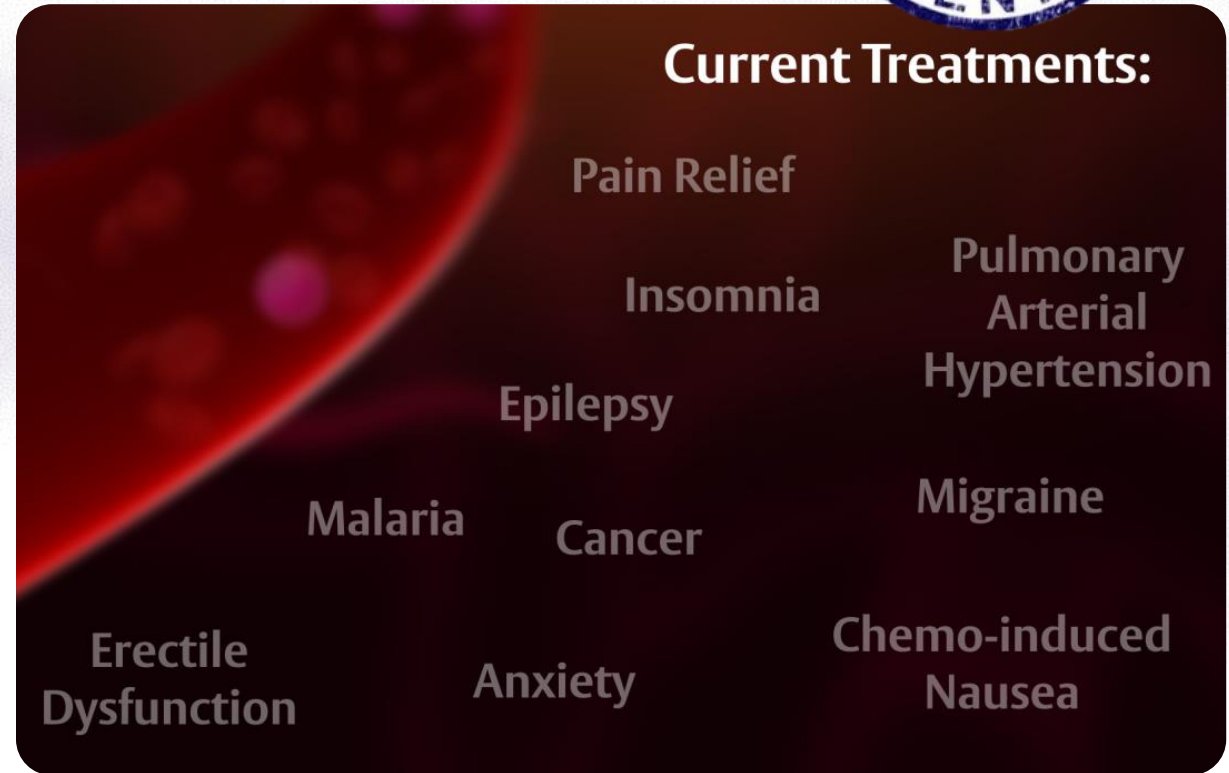


INTELLECTUAL PROPERTY

- Multiple patent families & more pending, covering:
 - 300 high-usage existing drugs formulated into oral sprays
 - Hydrotrope technology for better delivery of drugs across mucosa
 - Anagrelide use in cancer
 - Pump (air-activated) & aerosol (propellant-driven) sprays
 - Formulation and Use of Sildenafil in ED and PAH
 - Formulation and use of artemether spray in Malaria

PLATFORM TECHNOLOGY

- Core in-house competence in oro-mucosal reformulation
- Established process development and scale-up expertise



Board



Chairman

Paul Hopper

Over 25 years experience in the medical, healthcare & life sciences sectors. Focussed on start-up and rapid growth companies, he has served as either Founder, Chairman, non-executive director or CEO, of more than fourteen companies in the US, Australia and Asia.



Managing Director

Stephen Carter

Experienced Pharmaceutical executive with over 30 years' management of pharmaceutical companies, drug development, manufacturing, marketing and commercialisation in early-stage to mature companies. Previous senior roles (GM/MD or Chairman) in Delta West, Upjohn, Pharmacia, Pfizer, Solbec, Delmedica, and Colltech.



Executive Director

David Phillips

Senior Business Development Executive with over 30 years in the healthcare industry. Including 16 years in GSK, 12 years in Biotech and as Managing Partner of SR One (GlaxoSmithKline's Corporate Venture Fund). David has been responsible for over 50 Pharma/Biotech deals and 10M&A transactions.



Director

David Simmonds

David was a senior audit partner with Ernst & Young from 1989 to 2017. From 2008 to 2013, David led the Capital Markets desk in Australia with responsibility for overseeing or reviewing all Australian cross border fundraisings. David is currently a member of the Board of MS Research Australia

Scientific Advisory Board



Prof Stephen Watson

Prof Watson is British Heart Foundation Chair in Cardiovascular Sciences and Cellular Pharmacology in the University of Birmingham. He leads the Birmingham Platelet Group which consists of between 30 and 35 researchers including 8 group leaders. The focus of Prof Watson's research is on cell surface receptors and their signaling pathways in blood platelets. He is an editor of Trends in Pharmacological Sciences (TiPS), a former Editor of the British Journal of Pharmacology, and was Editor of the first 8 Editions of the TiPS Receptor Nomenclature Supplement. Prof Watson was appointed to the Academy of Medical Sciences in 2002.



Dr Richard Franklin

Dr Richard Franklin gained his PhD from Surrey University in the UK in Drug Metabolism and Pharmacokinetics and subsequently worked in research and development in the pharmaceutical industry. Dr Franklin has worked for several major drug companies including Glaxo, Wyeth, Sterling Winthrop, & AstraZeneca. Latterly he was head of New Product Innovation at Shire Pharmaceuticals where he is credited with filing over forty patents on potential new drug products.



Assoc Prof Nailin Li

Associate Professor, MD, PhD
Karolinska Institutet, Sweden

Dr Nailin Li received his doctoral education at Karolinska Institutet in Sweden (1999). After a post-doc training at Karolinska Institutet and University of Leicester in UK, he was promoted to associate professor in 2003. He currently works as a senior researcher and Director of Karolinska Institutet doctoral programme in cardiovascular research. Dr Li's main research interests are thrombotic and inflammatory mechanisms in atherosclerosis, platelet angiogenetic activities in arterial remodelling and cancer progression, and clinical evaluation of antiplatelet drugs. Dr Li is an internationally recognized researcher in platelet functional studies and platelet-T effector cell interactions.



Professor Anthony Fox

Is a physician with over 25 years' experience in the pharmaceutical industry with both large and small companies. His industrial positions included Glaxo where he led the US clinical development of oral, intranasal and subcutaneous sumatriptan (Imitrex®; Imigran®) for migraine and cluster headache. He is a Visiting Professor at King's College London. He is a chartered biologist and a Fellow of the Royal College of Physicians as well as its Faculty of Pharmaceutical Medicine; he is also an Adjunct Associate Clinical Professor at the University of California, San Diego. He is on the editorial boards of several journals, and co-edits Principles and Practice of Pharmaceutical Medicine. Professor Fox has published many research papers concerning migraine therapies.



Dr. Roger Cady

Associate Executive Chairman of the National Headache Foundation since February, 2010. Dr. Cady is VP Neurology of Alder BioPharmaceuticals. He served as the Medical Director of the Headache Care Center and was the founder of Clinvest Research and Primary Care Network. He also served as Medical Director for the Shealy Institute in Springfield, Missouri.

During his career, Dr. Cady has authored over 250 scientific papers and received numerous awards. Dr. Cady is a Fellow of the American Headache.

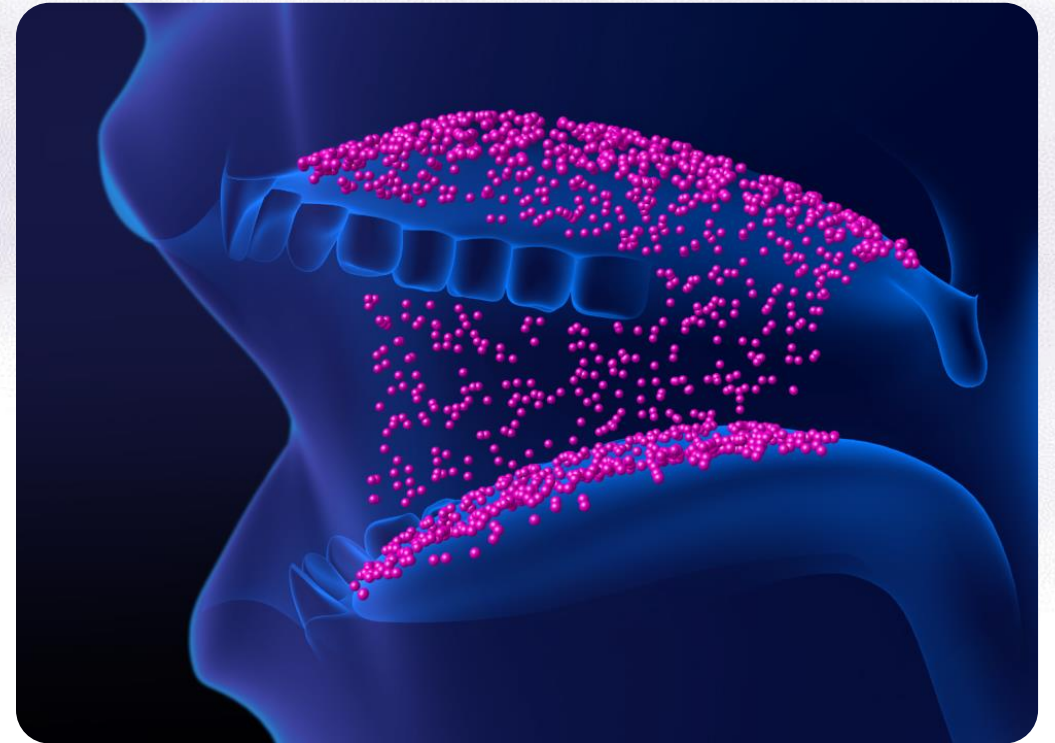


Assoc. Prof. Eric Chung

Associate Prof. Chung serves as a consultant urological surgeon working in Brisbane Australia. He is a certified Fellow of the Royal Australasian College of Surgeons (RACS) and Urological Society of Australia and New Zealand (USANZ). He is the Chair of the Andrology Group in USANZ

Summary Highlights

- Unique platform technology for reformulating existing billion-dollar drugs for oral delivery
- Faster, potentially smaller doses & safer delivery for ex-blockbuster drugs
- Large target markets including patients suffering migraine, anxiety, erectile dysfunction, nausea and cancer
- Reformulation into an oral spray offers fast approval & significantly lower cost under the FDA'S accelerated 505 (b)(2) pathway to approval
- Promising opportunity to take a drug approved for blood disorder & convert it to an oro-mucosal spray cancer drug
- Technology validated with licensing deals completed with Teva and Mitsubishi
- Robust intellectual property portfolio with over 50 patents
- Experienced leadership team with modest operating overheads
- Attractive valuation with near-term value enhancing events



SUDA

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