



# SUDA Investor Presentation

30<sup>th</sup> March 2021



# Company Highlights

- **Refreshed Board and Management Team:** Actively seeking new deal flow for technologies with a focus on oncology and the central nervous system
- **Unique Platform Technology – OroMist™:** Reformulate existing billion-dollar drugs for oral delivery, faster path to market, which can create cost and time savings
- **TGA Approval Secured for ZolpiMist:** ZolpiMist received TGA approval July 2020 for the treatment of short-term insomnia – assists licensed territories covering **400 million people**
- **Large Target Markets:** Cancer<sup>1</sup> (US\$38b for immuno-oncology by 2025 ), insomnia<sup>2</sup> (US\$7.5b by 2026), migraine<sup>3</sup> (US\$10.5b by 2025), and medical grade cannabis<sup>4</sup> (US\$44b by 2024)
- **We Are Well Capitalised:** As of December 31<sup>st</sup> 2020, SUDA had \$5.47 million cash

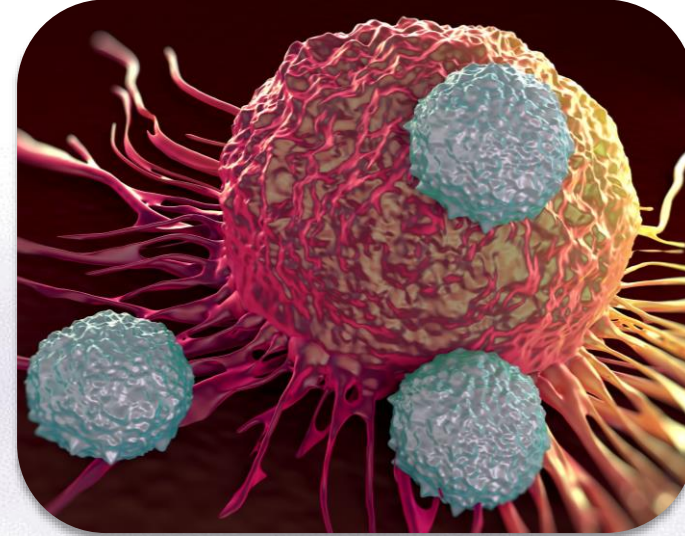
1. <https://www.polarismarketresearch.com/press-releases/immuno-oncology-i-o-market>

2. <https://www.persistencemarketresearch.com/market-research/insomnia-treatment-market.asp>

3. <https://www.industryarc.com/Report/15694/anti-migraine-drugs-market.html>

4. <https://www.researchandmarkets.com/reports/4763121/medical-cannabis-market-global-industry-trends>

## Focus – Oncology and CNS



# Company Overview

## Financial Snapshot

ASX CODE	SUD
Market capitalisation*	\$16.5 million
Shares on issue	386.66 million
52-week low / high	\$0.025 / \$0.97
Cash (31 <sup>st</sup> Dec 2020)	\$5.47 million
Sector	Biotechnology

## Major Shareholders

Shareholder	Ownership (%)*
ZERRIN INVESTMENTS PTY LTD	15,000,000 (3.90%)
KAMALA HOLDINGS PTY LTD	9,100,000 (2.37%)
UBS NOMINEES PTY LTD	8,485,693 (2.21%)
SCINTILLA STRATEGIC INVESTMENTS LIMITED	7,666,667 (1.99%)
CHELSEA INVESTMENTS (WA) PTY LTD	6,500,000 (1.69%)

\* as of March 26, 2021



# Technology Highlights - OroMist™

- **Clinical Data<sup>1</sup> Demonstrates:**

- Increased Bioavailability
- The drug bypasses the gastro-intestinal tract preventing breakdown so patients can potentially take less drug

- **Faster onset of action:**

- The drug can enter the blood stream directly by crossing the lining of the mouth

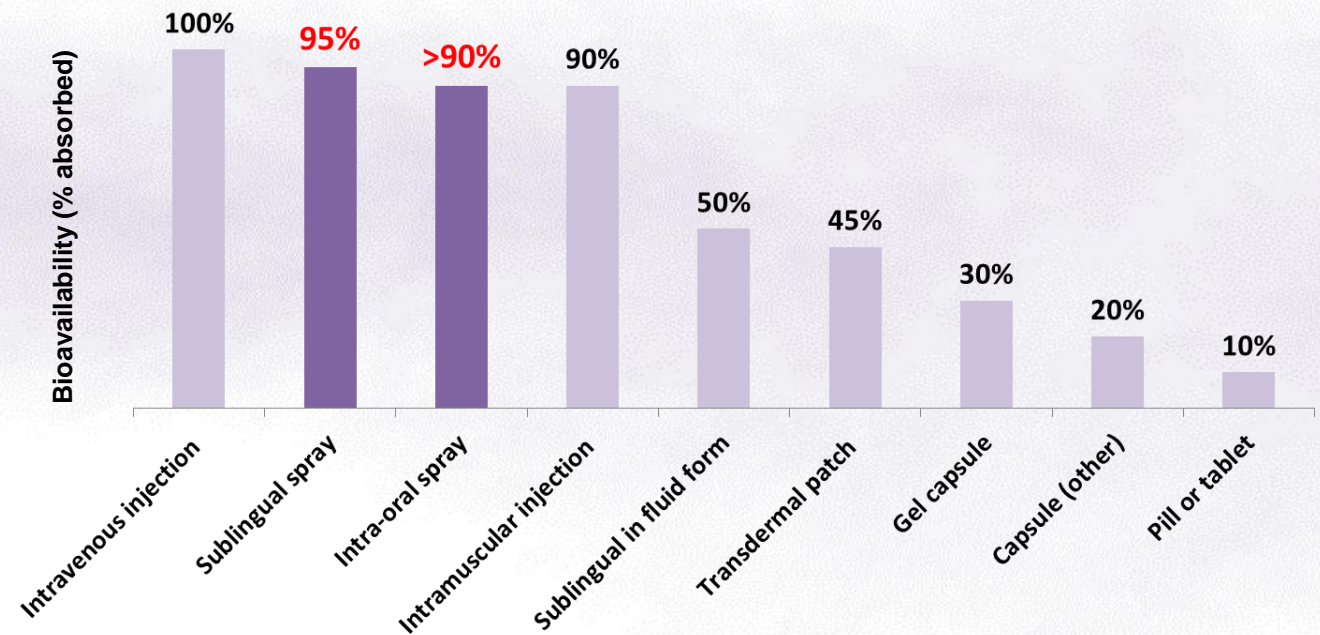
- **Easier to administer:**

- Patients suffering from nausea may be able to effectively take their medication
- Patients not amenable to taking medication can be treated – i.e. seizure, dysphagia, paediatrics

- **Increased Compliance:**

- An oral spray removes the need for injection and the requirement to swallow or inhale

## *The most effective drug dosing methods*



1. Clinical data available for Estradiol, Clemastine fumarate, Sildenafil and Loratadine.

Source: Physician's Desk Reference, NPPDR, No. 18:676, 1997

# IP & Platform Strategy

## INTELLECTUAL PROPERTY

- Multiple patent families covering:
  - Many high-usage existing drugs formulated into oral sprays
  - Hydrotrope technology for better delivery of drugs across the oral mucosa
  - Anagrelide use in metastatic disease – granted in Europe, Japan and Australia

## PLATFORM TECHNOLOGY

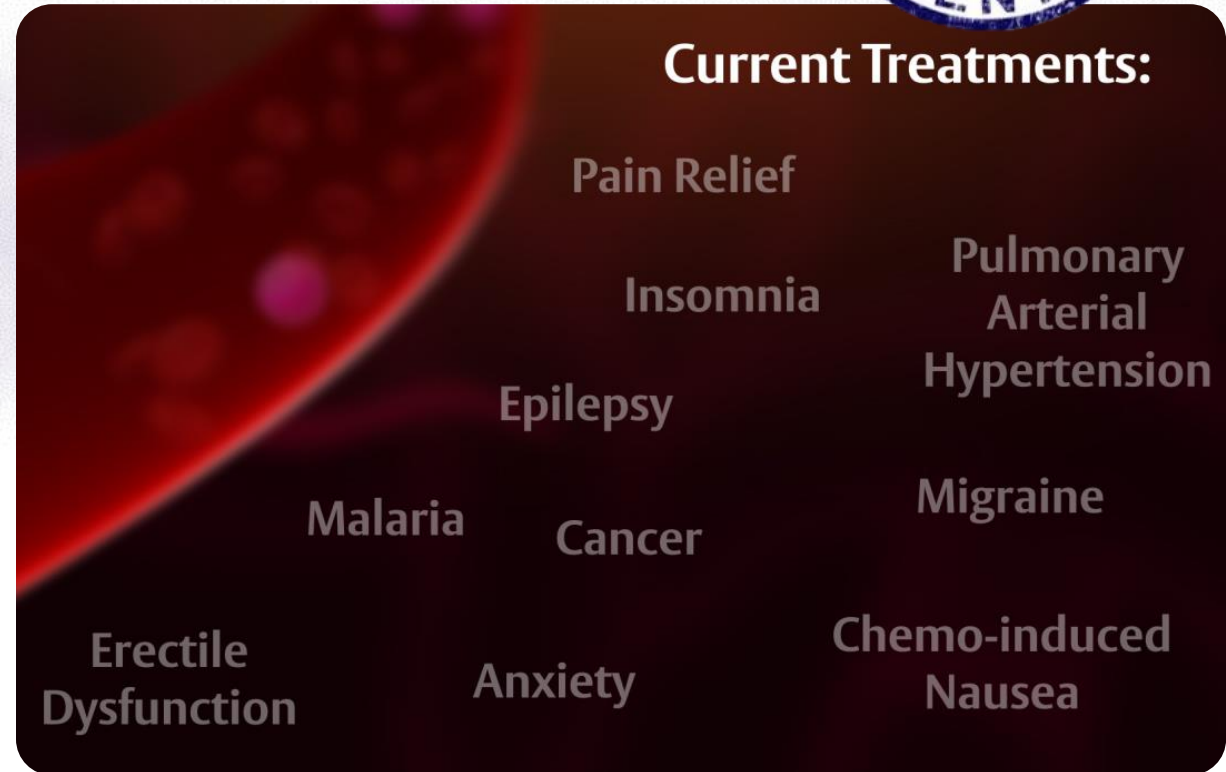
- Core in-house competence in oro-mucosal reformulation
- Established process development and scale-up expertise

## SOURCING NEW INTELLECTUAL PROPERTY

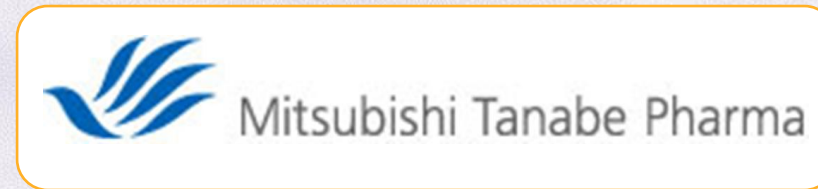
- SUDA is looking to acquire additional intellectual property in its areas of interest, oncology and the central nervous system



### Current Treatments:

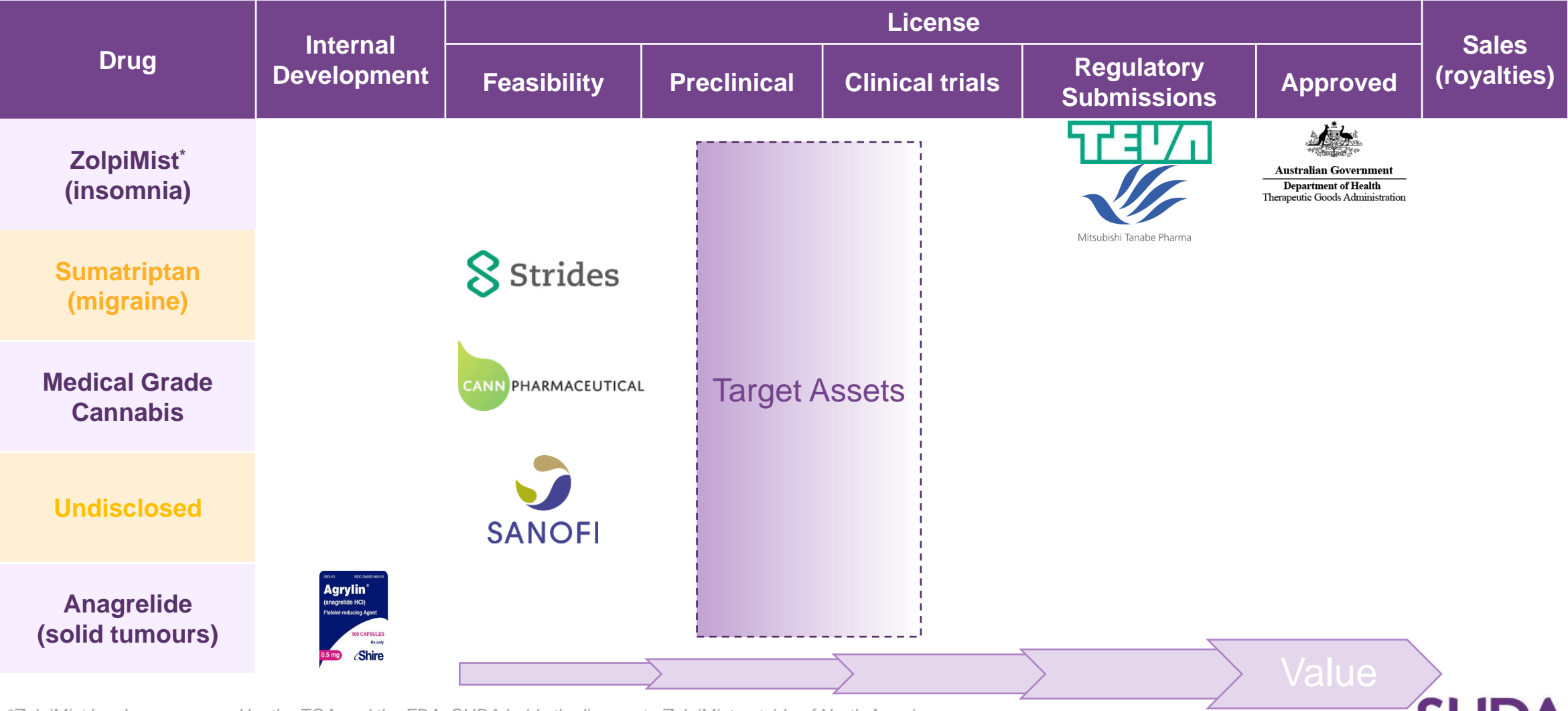


# Pharmaceutical Partnership Strategy





# Business Strategy - Develop and License

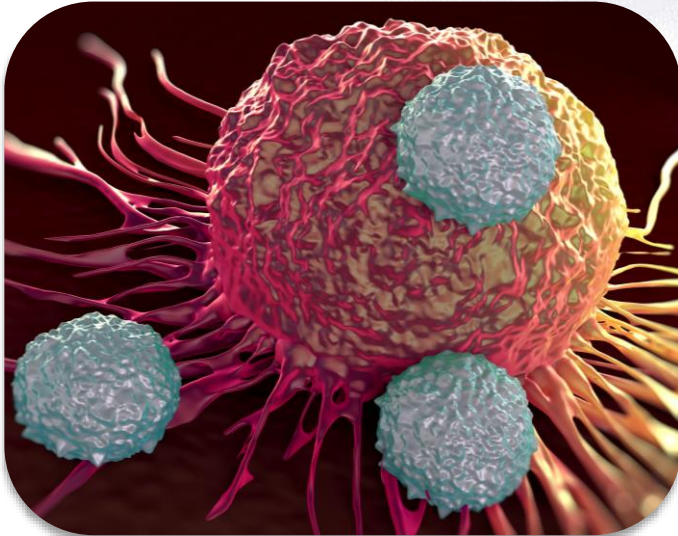


\*ZolpiMist has been approved by the TGA and the FDA. SUDA holds the licence to ZolpiMist outside of North America

# Expanding our Portfolio

- Over 18-24 months SUDA has refreshed the board and senior management group
- The team has expertise in sourcing, evaluating and acquiring novel technologies
- SUDA's key areas of focus are oncology and the central nervous system
- SUDA will continue to source deal flow and look to add new technologies to the portfolio
- Discussions for target assets are ongoing

## *Oncology*



## *Central Nervous System*





# Board & Senior Management



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. Mr Hopper has founded, or technology seeded, six companies on the ASX and Nasdaq.



CEO & Managing Director

Dr. Michael Baker

Over 15 years experience in scientific research, drug development and venture investing sectors. He was an Investment Manager with the leading Australian life science fund, BioScience Managers, responsible for deal sourcing from networks, conferences, universities and research institutes. He also conducted due diligence to shortlist investment opportunities and played an active role in managing portfolio companies.



Executive Director

David Phillips

Senior Business Development Executive with over 35 years in the healthcare industry. Including 23 years in GSK, 12 years in Biotech and as Managing Partner of SR One (GlaxoSmithKline's Corporate Venture Fund). During this period Mr Phillips was a member of the investment committee reviewing greater than 30 deals. David has been responsible for over 50 Pharma/Biotech deals and 10 M&A transactions.



Director

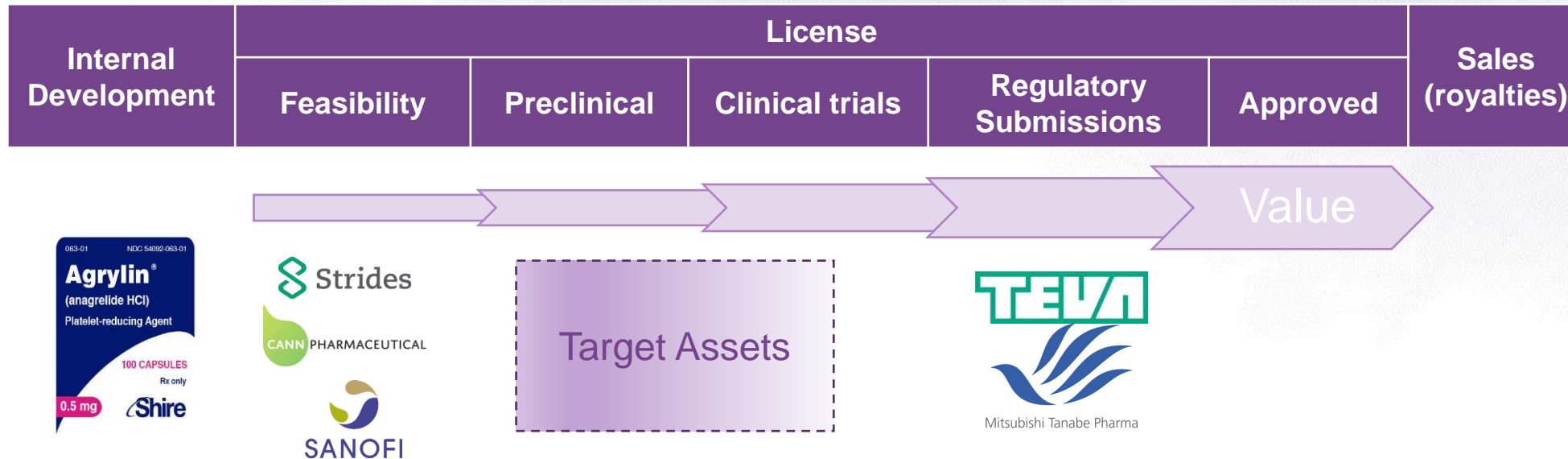
David Simmonds

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 was a member of the Board of MS Research Australia.



# Our Focus For The Year Ahead

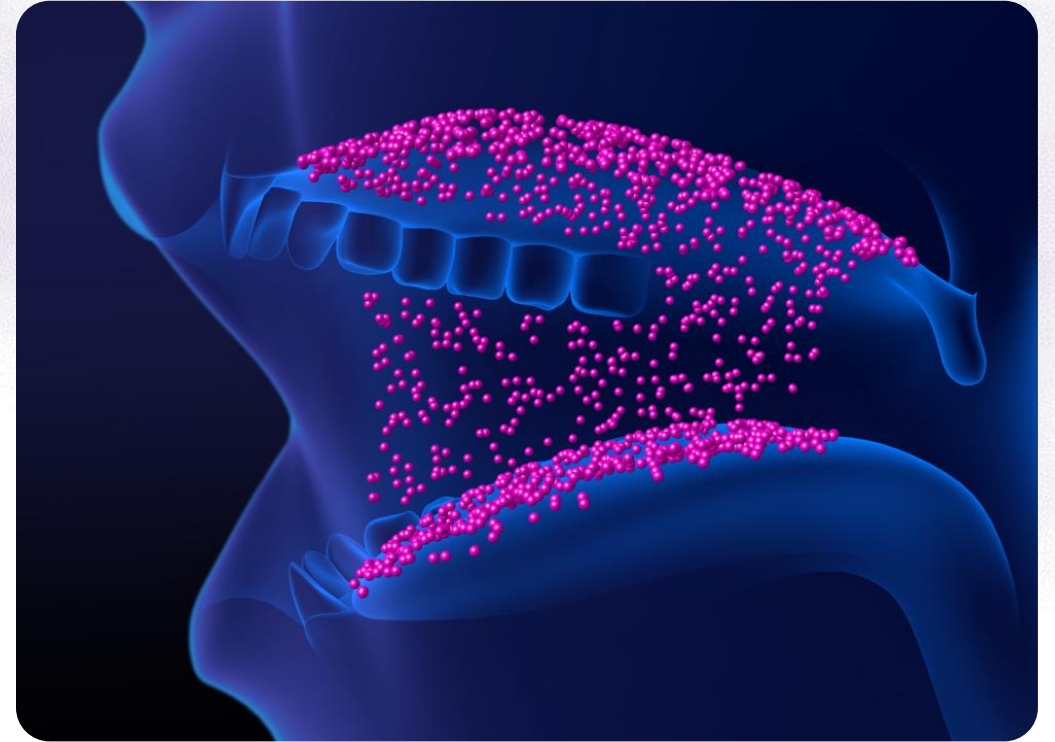
- ZolpiMist commercialization – assist current partners and secure additional partnerships
- Work with MedPharm to stabilise the anagrelide formulation and initiate preclinical studies
- Continue development work with our partners - Sanofi, Strides Pharma and Cann Pharma
- Acquire and integrate new assets – oncology and CNS
- Manage costs
- Maintain shareholder communications and focus on investor confidence





# Strategic Future

- SUDA will continue to source, evaluate and acquire new technologies
- Continue to expand the team with deep Biotechnology/Drug Development/Pharma experience
- Build out the intellectual property portfolio – patents and knowhow
- Build out the OroMist platform to reformulate existing billion-dollar drugs for oral delivery by creating partnerships with big pharma
- We have strong support from our current shareholders and we will continue to ensure that our shareholders are prioritised





# Anagrelide - Reformulating to Treat Cancer



- **Anagrelide:** An approved generic drug to treat a rare blood disorder
- **Research Shows:** Cancer patients with high platelet counts have a poor prognosis and lowering platelets may increase survival rates
- **Making Anagrelide Safer:** The capsule has unwanted side effects on the heart, and an injectable formulation does not exist
- **Preclinical Animal Studies Demonstrate:** An oral spray may reduce exposure to the cardiostimulatory metabolite
- **Reformulation Work:** Conversion into an oral spray is ongoing and SUDA has contracted the services of MedPharm, a global CDMO that specializes in topical and transdermal delivery
- **SUDA Owns the Intellectual Property:**
  - “Prevention and treatment of metastatic disease in thrombocytotic cancer patients”
  - Granted in Europe, Japan and Australia
- **We Have The Team:** Dr Richard Franklin is the Project Director, who was involved in progressing Agrylin® through to approval throughout Europe. We also recently appointed Dr Anil. K Sood from the University of Texas MD Anderson Cancer Center to our Scientific Advisory Board



Project Director

## Dr Richard Franklin

Dr Franklin gained his PhD from Surrey University in the UK in Drug Metabolism and Pharmacokinetics. He has worked for several major drug companies including Glaxo, Wyeth, Sterling Winthrop, & AstraZeneca. He was head of New Product Innovation at Shire Pharmaceuticals and involved in the development and registration of anagrelide for the treatment of essential thrombocythemia in Europe.



# Anagrelide Highlights

Anagrelide has been approved to treat Essential Thrombocythemia in the US and the EU

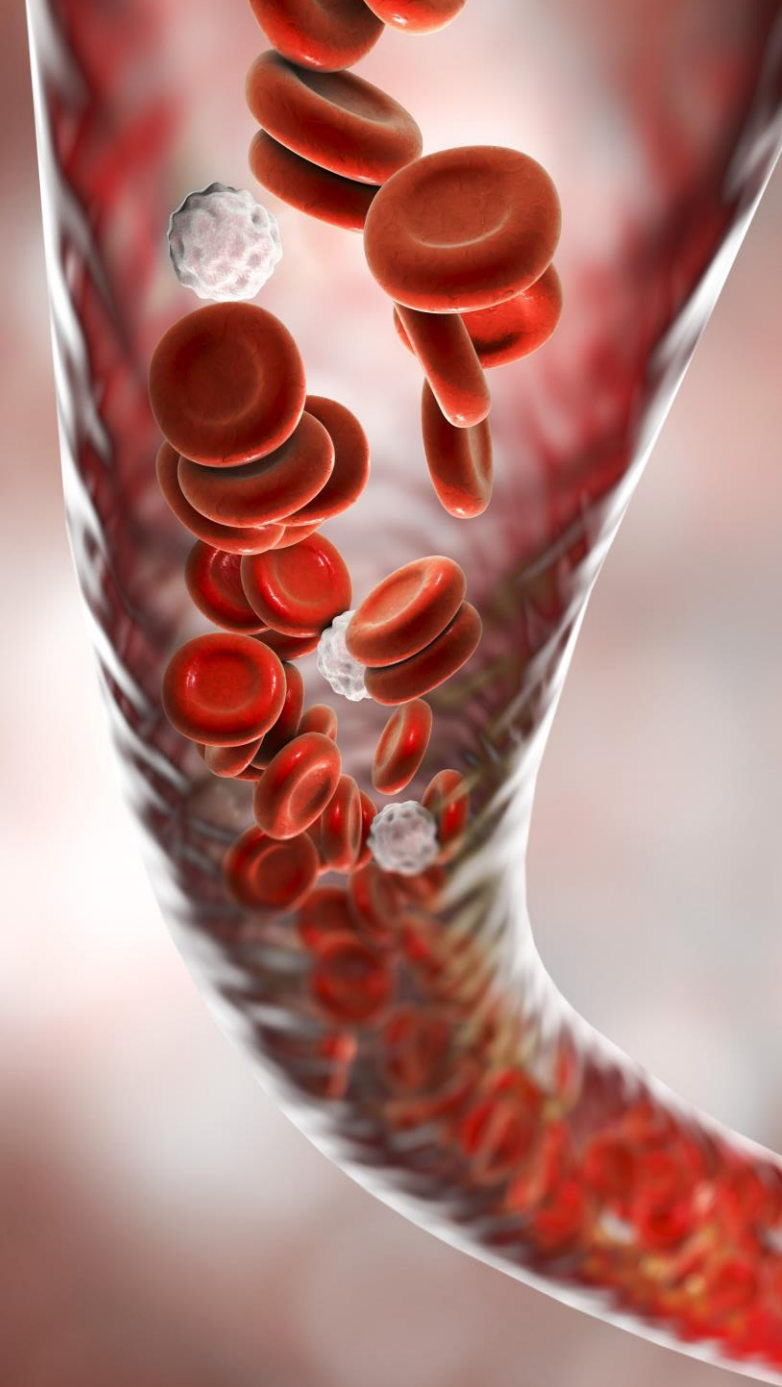
The range of solid tumours that present with increased platelet levels suggest significant therapeutic potential

Anagrelide has been in clinical use for >20 years and has a demonstrated safety profile

The production of a cardiotoxic metabolite following administration of the capsule form of the drug limited uptake and sales of anagrelide

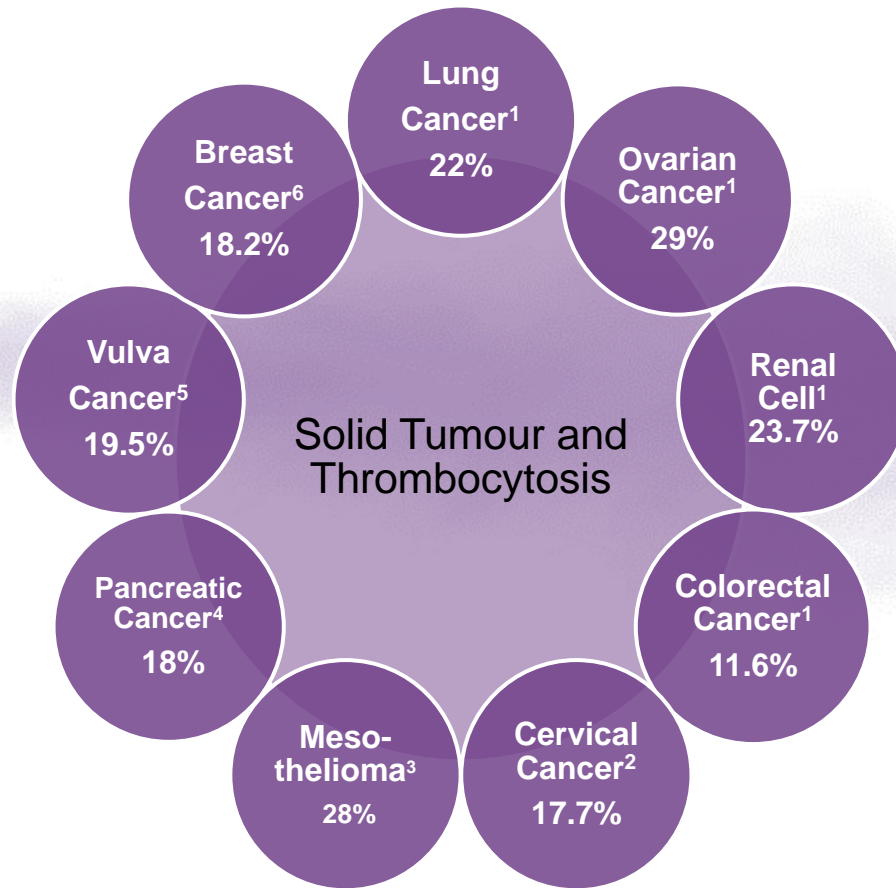
An oral spray version of the drug results in increased bioavailability and a potential reduction in exposure to the cardiostimulatory intermediate

SUDA is the only company to hold the intellectual property for use of anagrelide in the treatment of metastatic disease





# Broad Technology Applicability



## Multiple Opportunities

- Thrombocytosis is implicated in a number of different cancer types
- Increased platelet levels are prognostic for poor survival rates in numerous cancer types

## Large Patient Groups

- Many cancer types have a prevalence of 12-28% of patients presenting with elevated platelets

## Significant Commercial Opportunity

- Anagrelide presents a significant market opportunity with a targetable market of >6 million patients per annum with increased platelet levels and solid tumors
- SUDA's current target indications include non-small cell lung carcinoma, ovarian cancer, bowel cancer and renal cancer

1. Oncofocus - Secondary desktop research report

2. Hernandez et al., (1992) Poor prognosis associated with thrombocytosis in patients with cervical cancer

3. Olsen et al., (1988) Thrombocytosis in patients with malignant pleural mesothelioma

4. Chadha et al., (2015) Paraneoplastic thrombocytosis independently predicts poor prognosis in patients with locally advanced pancreatic cancer

5. Lavie et al., (1999) Thrombocytosis in women with vulvar carcinoma

6. Stravodimou et al., (2013) Thrombocytosis as a Prognostic Factor in Metastatic Breast Cancer



# Increased Platelets = Reduced Cancer Patient Survival Rates

Cancer	Overall survival (months); high platelet vs low platelet*
Lung <sup>1</sup>	38 vs 63
Ovarian <sup>2</sup>	31.2 vs 55.8
Pancreatic <sup>3</sup>	10.2 vs 19.0
Breast <sup>4</sup>	12.5 vs 26

- Thrombocytosis is implicated in multiple cancer types
- Cancer patient survival rates are decreased in the background of increased platelets
- Anagrelide presents a significant opportunity to decrease platelet levels and increase lifespan in cancer patients

*\*The overall survival figures are the results of specific studies, which may not be entirely representative of the cancer as a whole.*

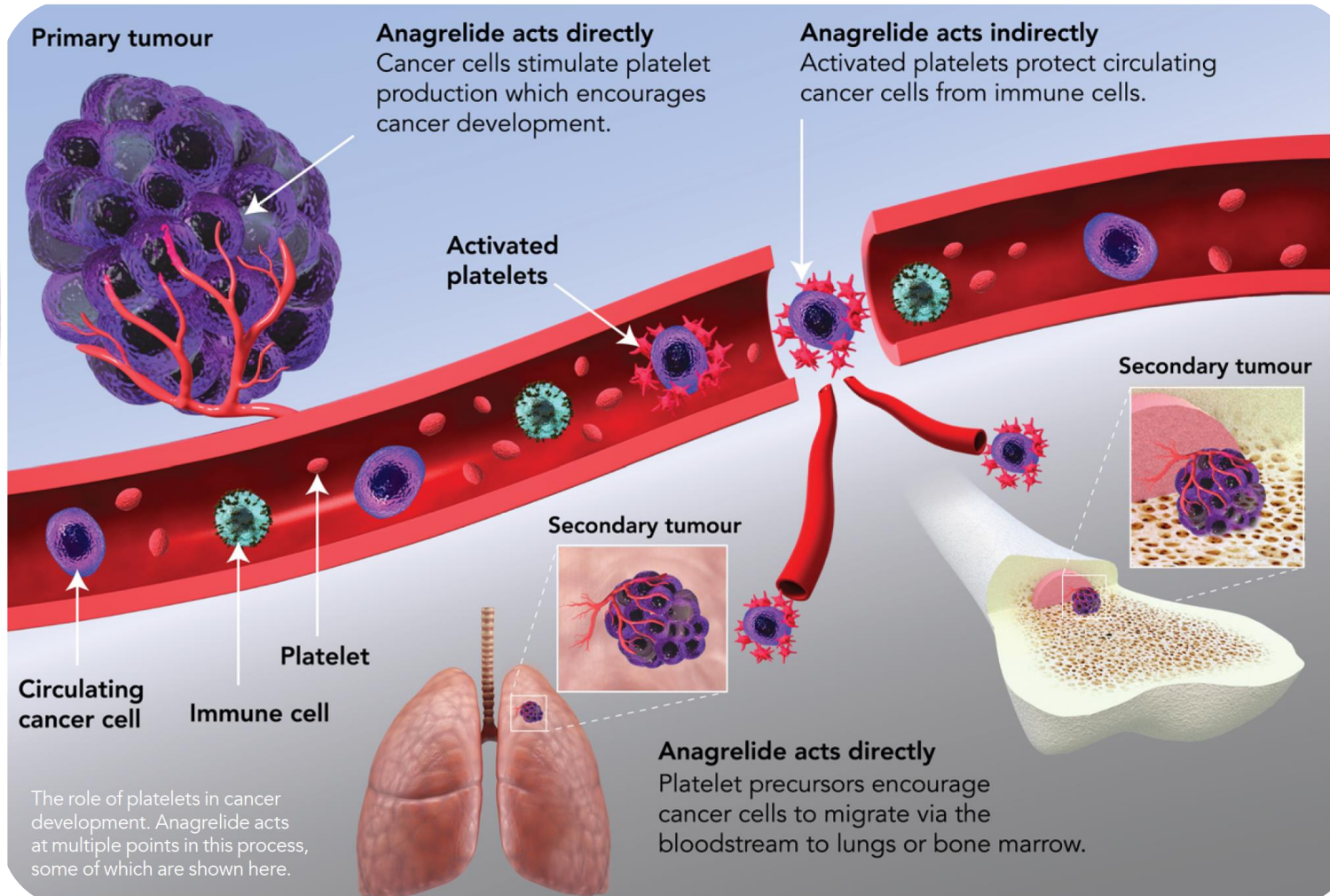
*1. Maraz et al., (2013) Thrombocytosis Has a Negative Prognostic Value in Lung Cancer*

*2. Stone et al., (2012) Paraneoplastic Thrombocytosis in Ovarian Cancer*

*3. Chadha et al., (2015) Paraneoplastic thrombocytosis independently predicts poor prognosis in patients with locally advanced pancreatic cancer*

*4. Stravodimou et al., (2013) Thrombocytosis as a Prognostic Factor in Metastatic Breast Cancer*

# Why Anagrelide is Unique



- Anagrelide blocks cancer cell stimulation of platelet production which otherwise encourages cancer development
- Anagrelide acts directly by blocking cancer cell migration from the blood stream to lungs or bone marrow
- Anagrelide acts indirectly by reducing platelet numbers which can protect circulating tumour cells from immune (T) cell attack



# Improving Anagrelide's Safety Profile

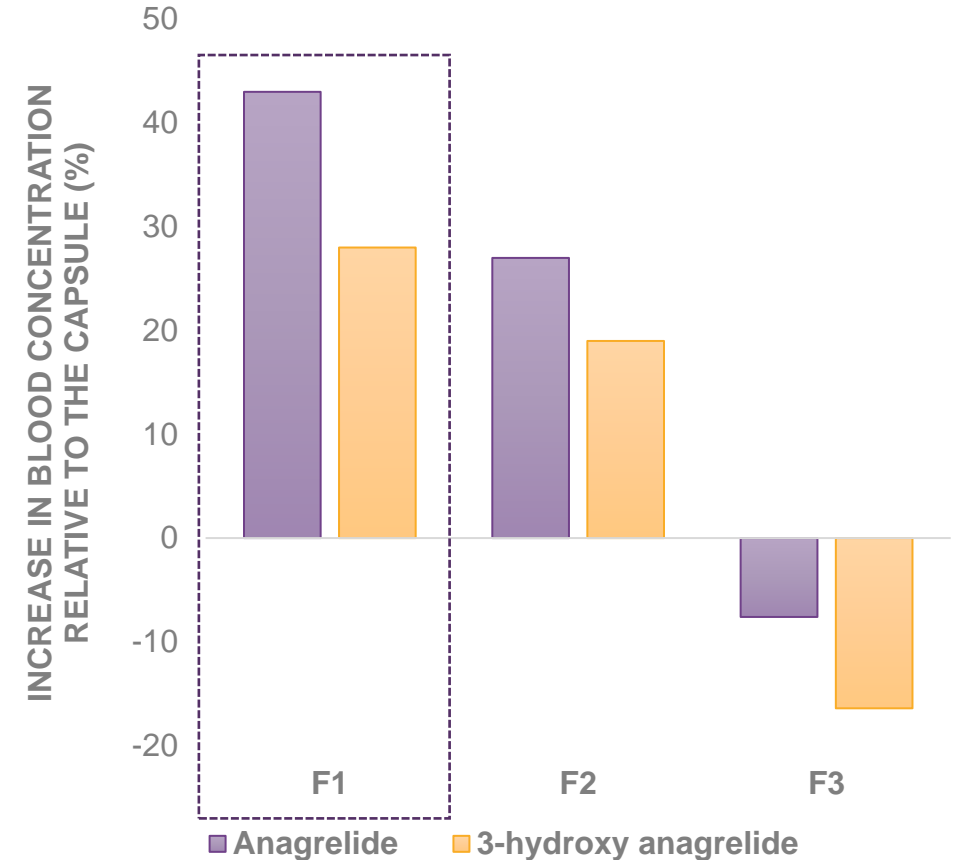
## Background

- Anagrelide was approved by the FDA in 1997 and the EMA in 2004
- From clinical data, serious cardiovascular events, including congestive heart failure, were reported.
- In a recent study that followed ET patients for 25 years, ~40% of the patients reported palpitations as a side effect<sup>1</sup>
- The cardiostimulatory effects of anagrelide limited its uptake capping peak sales to \$153 million in 2004<sup>2</sup>

## A safer way to dose patients with anagrelide

- SUDA have produced an oral spray version of anagrelide
- In animal models, the oral spray significantly increases bioavailability of the drug in comparison to the approved capsule
- An increase in 3-hydroxy anagrelide is observed but it is not as pronounced as the parent drug. A lower dose could be administered, and a safer product produced to treat cancer patients

1. Mazzucconi et al., (2020) Anagrelide in Essential Thrombocythemia (ET): Results from 150 patients over 25 years  
2. [http://www.pharmatimes.com/news/generic\\_agrylin\\_hits\\_market\\_and\\_shire\\_998394](http://www.pharmatimes.com/news/generic_agrylin_hits_market_and_shire_998394)



Bioavailability of three anagrelide formulations delivered as an oral spray versus the approved capsule form of the drug. Oral spray F1 results in an increased bioavailability with a lesser increase of the cardiostimulatory metabolite, 3-hydroxy anagrelide



# Intellectual Property Strategy

## SUDA holds the IP for use of anagrelide to treat cancer

- “Prevention and treatment of metastatic disease in thrombocytotic cancer patients” Priority date 22 December 2014.
  - Europe Grant - June 2019 ✓
  - Japan Grant - May 2020 ✓
  - Australia Grant - Sept 2020 ✓
- SUDA continues to prosecute the patents in additional territories – including North America and China
- SUDA continues to produce data to support filing divisional patent applications and novel formulation patents



# Anagrelide Preclinical Development Strategy

## Formulation Development

- Convert anagrelide from solid dose form to an oral spray ✓
- Target delivery volume is a maximum of 140 µl for the optimal residency time ✓
- Optimize solubility and stability using an FDA acceptable dosing vehicle **Ongoing with MedPharm**

## Proof of concept

- Perform *in vitro* and *ex vivo* permeation studies to determine suitable base formulations ✓
- Include the best performing formulations in an *in vivo* canine study to test the hypothesis that an oral spray may be safer than the capsule ✓

## Toxicology

- A local irritation study will be performed to assess irritation at the site of delivery – single dose in a canine study did not cause irritation **To be completed**



# ZolpiMist® - Insomnia

- ZolpiMist is SUDA's spray version of the insomnia drug Ambien
- Ambien was Sanofi's blockbuster insomnia drug
- Short-term insomnia has an estimated prevalence of 9.5% in the US<sup>1</sup>
- TGA approval for ZolpiMist was granted in July 2020 – SUDA is continuing to advance discussions to secure an Australian partner
- SUDA has rest-of-world rights ex-North America, and License and Supply Agreements with Teva and Mitsubishi Tanabe Pharma Korea – populations of >400 million people
- Discussions with additional territories are underway
- SUDA to supply finished product to all parties



**ZolpiMIST™**  
(zolpidem tartrate) ORAL SPRAY 

- Innovative Delivery
- Rapid Spray Absorption
- Fast Asleep

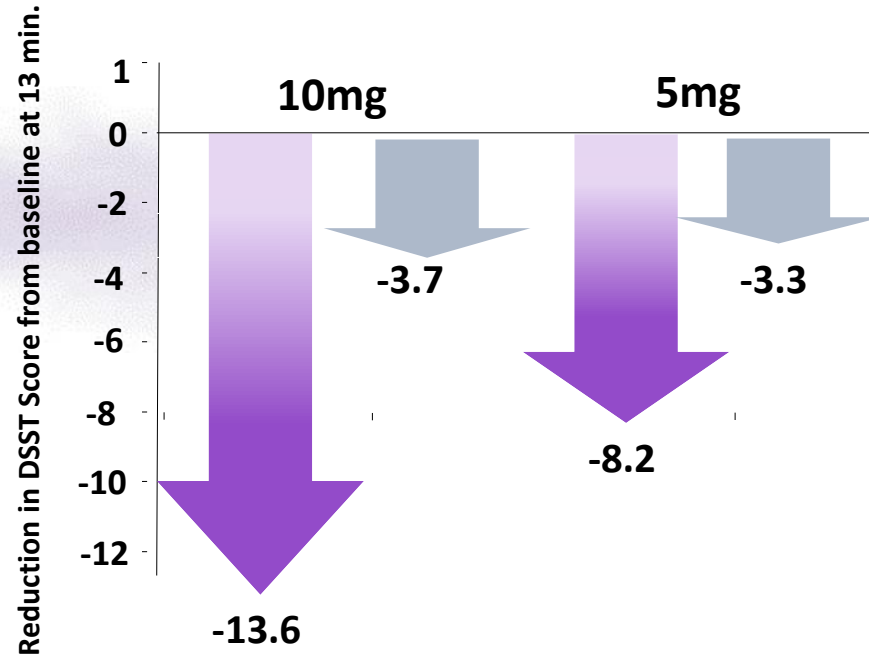


1. <https://www.ajmc.com/view/insomnia-overview-epidemiology-pathophysiology-diagnosis-and-monitoring-and-nonpharmacologic-therapy>

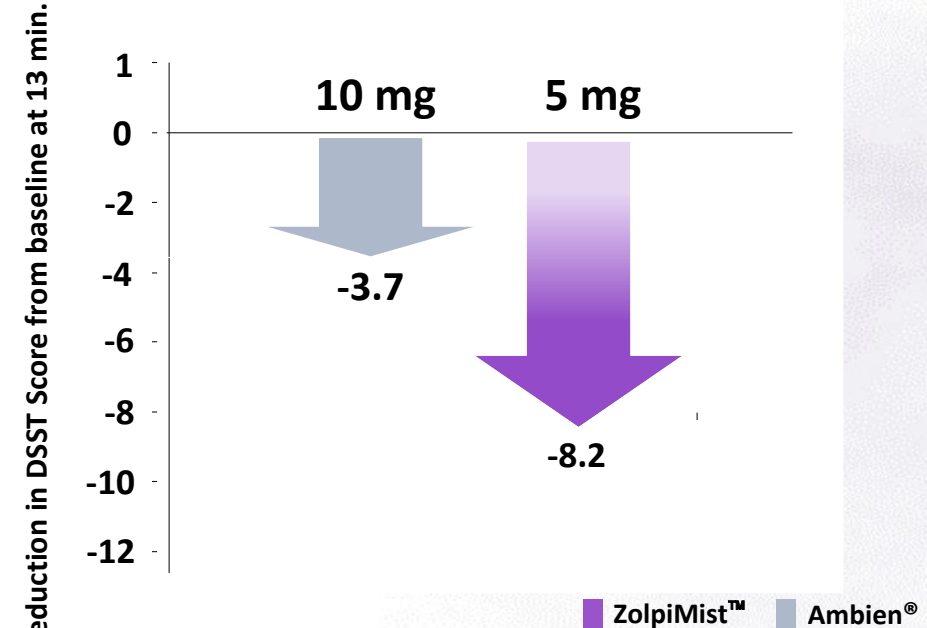


# ZolpiMist – Sleep Response

ZolpiMist™ induced sleepiness significantly faster than Ambien®



ZolpiMist™ 5mg induced sleepiness faster than Ambien® 10mg tablets



**ZolpiMist™ demonstrated significant faster onset of sedation compared to Ambien® tablets**

DSST = Digit Symbol Substitution Test

PD Endpoint - Changes in the DSST scores from baseline measurement to 13 and 23 minutes post-dosing

# Sumatriptan - Migraine



- Sumatriptan is the generic name for Glaxo's blockbuster migraine drug known as Imitrex. Similar class drugs were developed by Merck & J&J
- Migraine has a prevalence of ~13% in the US and ~15% in Europe making this a large opportunity for SUDA
- Attractive licensing deal for USA signed with large Indian pharma company, Strides Pharma, who focus on 505(b)(2) submissions
- Fully funded development program, including clinical trials, at a cost of >\$4m to be funded by Strides
- SUDA owns intellectual property covering
  - Mucosal Active Agent Delivery
- SUDA to supply finished product to Strides





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