



Building the future

Strategic partnership with SUDA
Pharmaceuticals

November 9th, 2018



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EXPANDING R&D INITIATIVES FOR THE US MARKETS

- ✓ Strides has significantly ramped up its R&D initiatives for the US markets and has now reached a run rate of 25 ANDA filings annually
- ✓ The established portfolio is a diversified basket of products in key dosage formats including soft gels, topicals, modified release products, tablets and includes several Para IV opportunities
- ✓ Execution of Strides' generic product pipeline for the US is nearing completion and is expected to have 150+ ANDA filings by 2021
- ✓ The company is now focusing on developing a portfolio of complex and specialty products including products filed under the 505B (2) regulatory pathway.
- ✓ The specialty portfolio will comprise of new products and reformulations of existing products targeted towards a efficient and effective delivery of drugs, leveraging unique drug delivery technology platforms
- ✓ The company through inhouse development and partnerships will build a portfolio of limited competition products offering exclusivity for a sustainable period.



80
GENERIC
ANDAs today



Generics
Portfolio focus on
diversified domains



150+
GENERIC
ANDAs by 2021



**Complex and
specialty**
Portfolio with focus
on novel drugs and delivery
with sustainable exclusivity





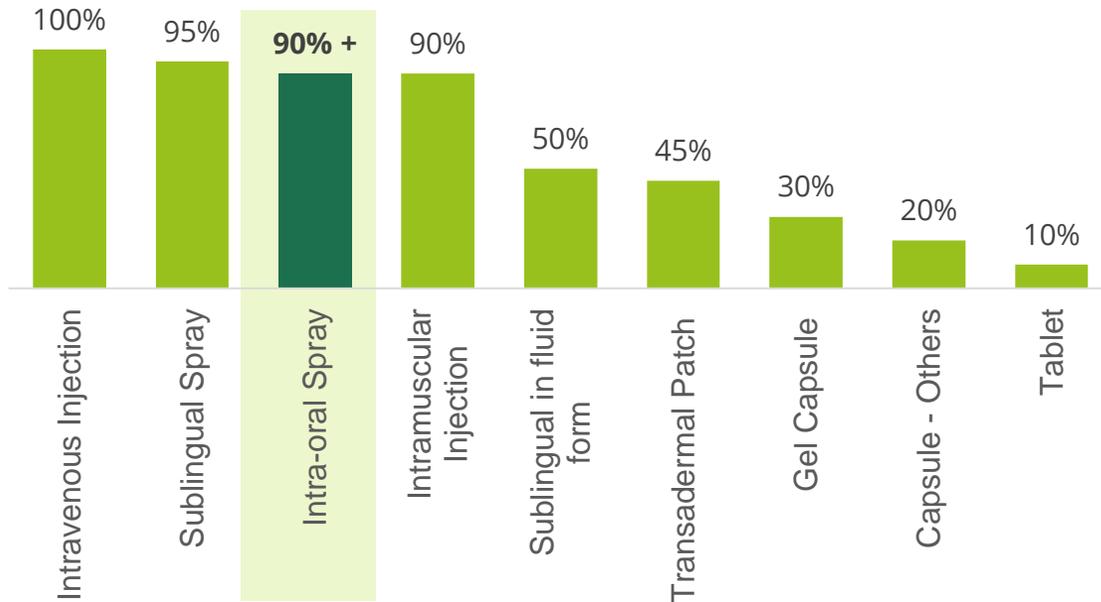
“ Global migraine drugs market size was valued at **US\$ 1.7 Bn** in 2017, US migrane drugs market pegged at **US\$ 1.2 Bn**”

TRANSACTION DETAILS

- ✓ Strides Pharma Science Limited (Strides) entered into exclusive product development, licensing and supply agreement with SUDA Pharmaceuticals Ltd (ASX: SUD) for its novel drug SUD-001H, an oral spray of sumatriptan to treat migraine headache for the US market
- ✓ SUD-001H is a first-in-class mint-flavoured oral spray formulation of sumatriptan (marketed in tablet form and in a nasal spray by GlaxoSmithKline under the brand name Imitrex®). Sumatriptan is one of the most widely used drugs for the treatment of acute migraine in adults
- ✓ SUDA will provide product development services for SUD-001H funded by Strides. SUDA to work with Strides team through joint committees to achieve successful USFDA approval for the product
- ✓ SUDA to receive an upfront cash payment of US\$ 0.4 Mn and a further payment of US\$ 0.6 Mn on reaching certain milestones including the pilot first-in-man clinical study, submission and approval of the product in the US. On commercial sales, SUDA will receive royalties plus a handling fee
- ✓ Strides to have a right of first refusal for additional territories including the European Union, Australia and New Zealand, Canada, South Africa and Japan.
- ✓ Partnership with SUDA is part of company's specialty portfolio buildout for the US market



Bioavailability across key dosage formats



Bioavailability is in excess of 90% via the oral mucosa

DRUG DELIVERY THROUGH ORO MUCOSAL SPRAY



Oral mucosa is the lining of the mouth, richly supplied by blood vessels. Oral cavity is ideal for systemic therapy and it avoids metabolism in liver and gut



SUDA has developed proprietary oro-mucosal drug delivery technology **“OroMist”** which enhances absorption of drug via oral mucosa



“OroMist” utilizes well-characterized combinations of hydrotropes to shield active drugs from inhibitory intercellular components



Ex-vivo and in-vivo studies have shown that hydrotrope technology significantly enhances bioavailability



Oro mucosal spray delivery technology enhances drug efficacy with better rate of absorption leading to reduction in dose level and dose variability



The technology has a faster onset of action and is more convenient in administration than other dosage format particularly for geriatric and pediatric use

Migraine

Migraines are headaches that typically last from 4-72 hours. Patients may experience nausea and vomiting as well as sensitivity to light or sound. Migraine sufferers frequently report throbbing pain that worsens with normal activity. According to the National Headache Foundation, more than 36 Mn Americans suffer from migraine. The drug market value of migraine treatments in the US was estimated to be ~US\$1.2 Bn in 2017.

Strides

Strides, listed on the BSE Limited (532531) and National Stock Exchange of India Limited (STAR), is global pharmaceutical Company headquartered in Bangalore. The Company has two business verticals, viz., Regulated Markets and Emerging Markets. The Company has a global manufacturing footprint with 7 manufacturing facilities spread across three continents including 5 facilities for Regulated Markets and 2 facilities for the Emerging Markets. The Company has strong R&D infrastructure in India with global filing capabilities and a strong commercial footprint across 100 countries. Additional information is available at the Company's website at www.strides.com

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 include ease of use, lower dosage, reduced side effects and faster response time. For more information, visit www.sudapharma.com





Thank You