



Investor Update on R&D Pipeline

24th August 2017

Disclaimer



Except for the historical information contained herein, statements in this presentation and the subsequent discussions, which include words or phrases such as "will", "aim", "will likely result", "would", "believe", "may", "expect", "will continue", "anticipate", "estimate", "intend", "plan", "contemplate", "seek to", "future", "objective", "goal", "likely", "project", "should", "potential", "will pursue" and similar expressions or variations of such expressions may constitute "forward-looking statements". These forward-looking statements involve a number of risks, uncertainties and other factors that could cause actual results to differ materially from those suggested by the forward-looking statements. These risks and uncertainties include, but are not limited to our ability to successfully implement our strategy, our growth and expansion plans, obtain regulatory approvals, our provisioning policies, technological changes, investment and business income, cash flow projections, our exposure to market risks as well as other risks. Sun Pharma Advanced Research Company Limited does not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date thereof.

Agenda



1 | **SPARC Strategy & Upcoming Milestones**
Anil Raghavan – CEO

2 | **Key Clinical Programs**
SiuLong Yao – Sr. V.P. Clinical Development & Operations

3 | **Drug Discovery Programs**
Nitin Damle – Sr. V.P. Discovery Biology & Pre-clinical R&D

4 | **Delivery System Innovations**
Yashoraj Zala – V.P. Formulation Development
Ajay Khopade – V.P. Formulation Development

5 | **Market Opportunity – Key Programs**
Narendra Lakkad – V.P. Business Development

6 | **Financial Update**
Chetan Rajpara – CFO

7 | **Q&A**

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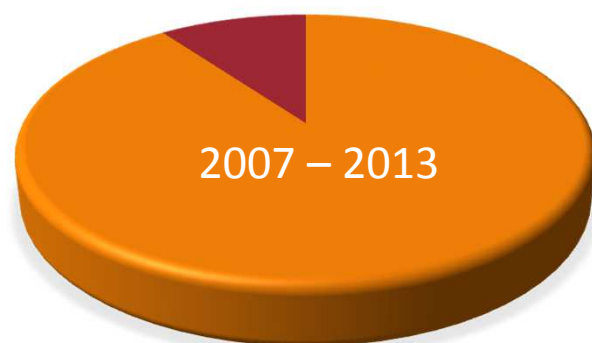
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SPARC's R&D strategy

Innovation with balanced risk



■ Delivery Systems Innovation ■ Validated Biology/Novel Chemistry ■ New Targets

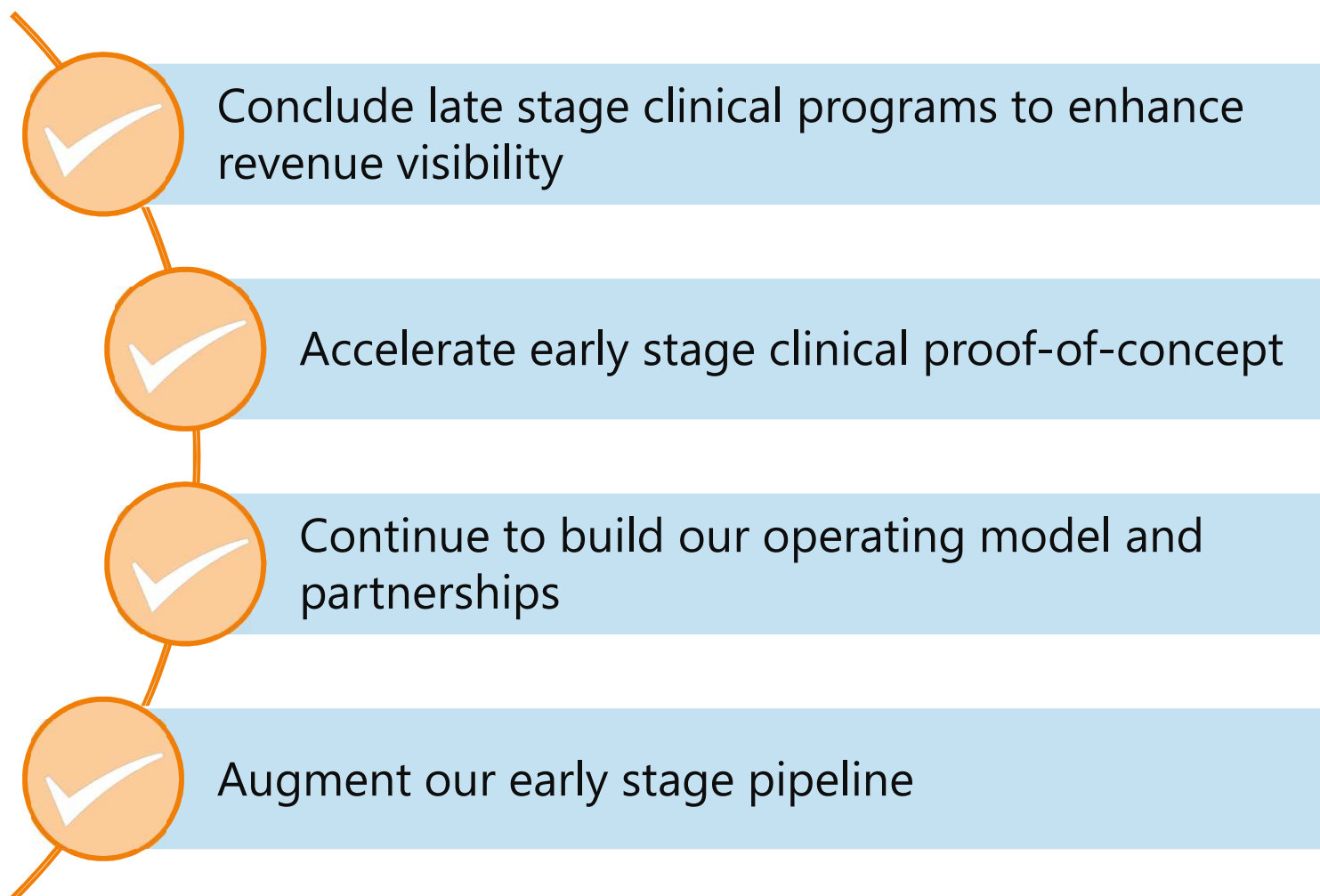
Oncology | CNS | Inflammation | Ophthalmology | Dermatology

- Leverage Formulation Development capabilities to pursue low hanging 505(b)(2) opportunities
- Tap validated mechanisms to create value with Medicinal Chemistry
- Narrow therapeutic area focus to build deeper competencies and developmental eco-systems
- Explore novel targets and new modalities with external collaborators to de-risk

Our short to medium term focus



Execute well while building competencies for the future



Focus on near term priorities

SPARC portfolio is gathering momentum



Key Milestones

Elepsia™ XR and Xelpros™

Initiated: Tech transfer of Elepsia™ XR and Xelpros™ to alternate manufacturing sites

Execution of pivotal studies of late stage assets

Completed: Salmeterol – Fluticasone DPI pivotal program, Baclofen GRS patient enrolment completed

Initiated: Taclantis™ pivotal BE study

Establish Clinical PoC

Completed: Brimonidine OD Phase 2, SDN-021 pilot PK study, SUN-K0706 Phase 1 PK in healthy subjects

Initiated: SUN-K0706 Phase 1 in CML patients

New Programs entering First in Human studies

Initiated: SUN-K0706 Phase 1 in Parkinson's Disease, S1PR1 Agonist Phase 1 in healthy subjects, SUN-597 Topical pilot study in Psoriasis

Cash Flow Management

Raised: Additional capital of INR 5000 mn through preferential warrants

Our operating model is evolving

Substantial investments to make SPARC future ready



Key Priorities

Capability Development

- Talent acquisition in Discovery Biology, Clinical Development and Regulatory Affairs
- Investments in upgrading the laboratory infrastructure and enabling technologies

Data Analytics as a strategic differentiator

- Computational and Analytical systems for enhanced efficiencies and predictability
- Investments in applications, infrastructure and human capital to build data competency for the future

Strategic Partnering for enhanced ideation

- Purposeful engagement with academic innovator communities to augment internal ideation
- Unique partnering proposition enabling SPARC to compete effectively in the marketplace for ideas

Scientific and Corporate Governance

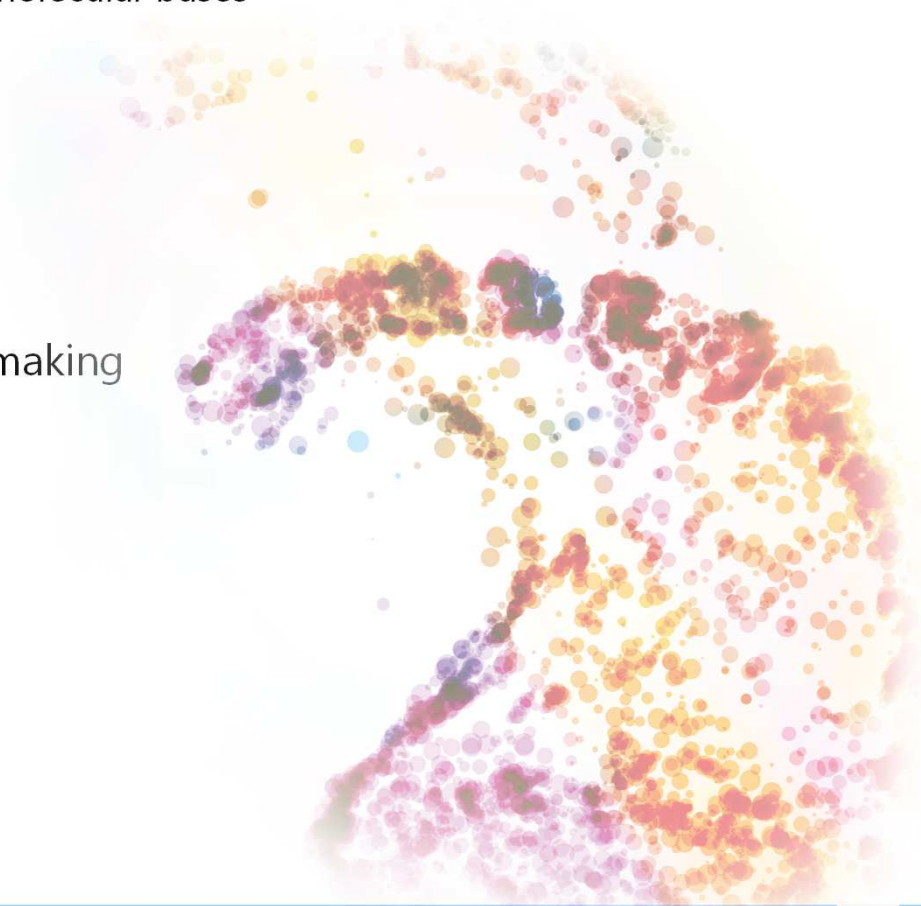
- Highly successful entrepreneurs with decades of experience in life sciences industry, Investment Banking added to the Corporate Board
- Collaboration with several accomplished scientific leaders through portfolio/program level advisory boards

Long-term portfolio strategy

Focused approach and translational discipline

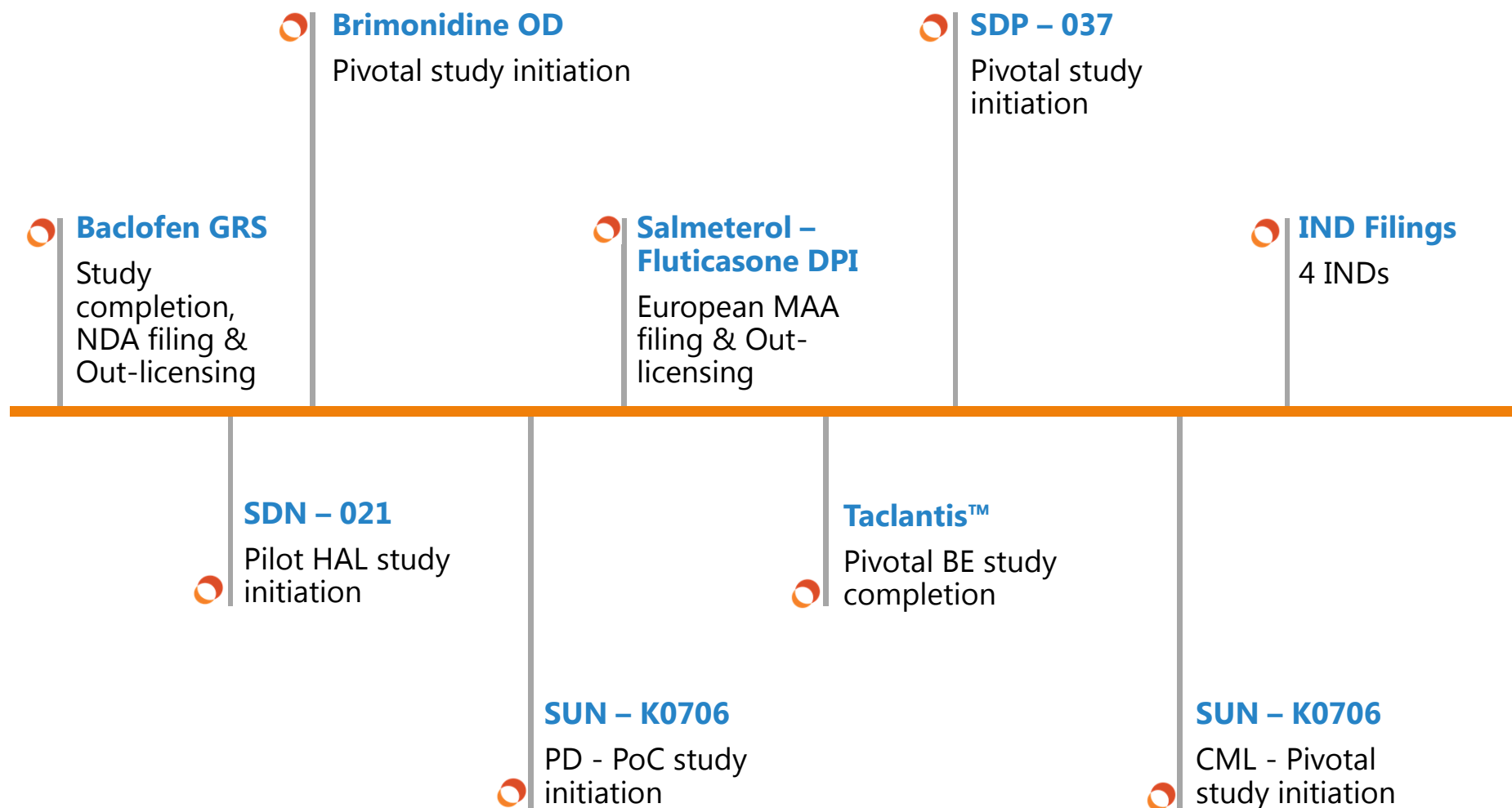


- Highly focused program selection
 - Treatment resistance in select cancers
 - Neurodegenerative conditions with clear molecular bases
 - Inflammation/Auto-immune disorders
 - Abuse deterrence
- Drug Delivery Platform development
- Selective expansion to novel modalities
- External validation in go/ no-go decision making
- Full pursuit of assets wherever possible



Setting expectations

Upcoming milestones for SPARC



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Baclofen GRS

Development on track as planned



- Recruitment completed for all Phase 3 studies

	Efficacy Study	Duration of Action Study	Safety Study
Number of Subjects	285	135	375
Status	<ul style="list-style-type: none">• Recruitment completed• LPO – Aug'17	<ul style="list-style-type: none">• Studies completed• Data under review	

- Data read-out in Oct'17
- Planned NDA filing by Q1FY19

Salmeterol – Fluticasone Dry Powder Inhaler

Summary of pivotal studies results



○ Peak Inspiratory Flow (PIF) study

- Mean PIF values well within the required range
- All subject groups successfully able to use SPARC device

○ High Dose Pharmacokinetic (PK) study

- Fluticasone and salmeterol PK comparable to Seretide® Accuhaler® PK

○ Low Dose Pharmacokinetic (PK) study

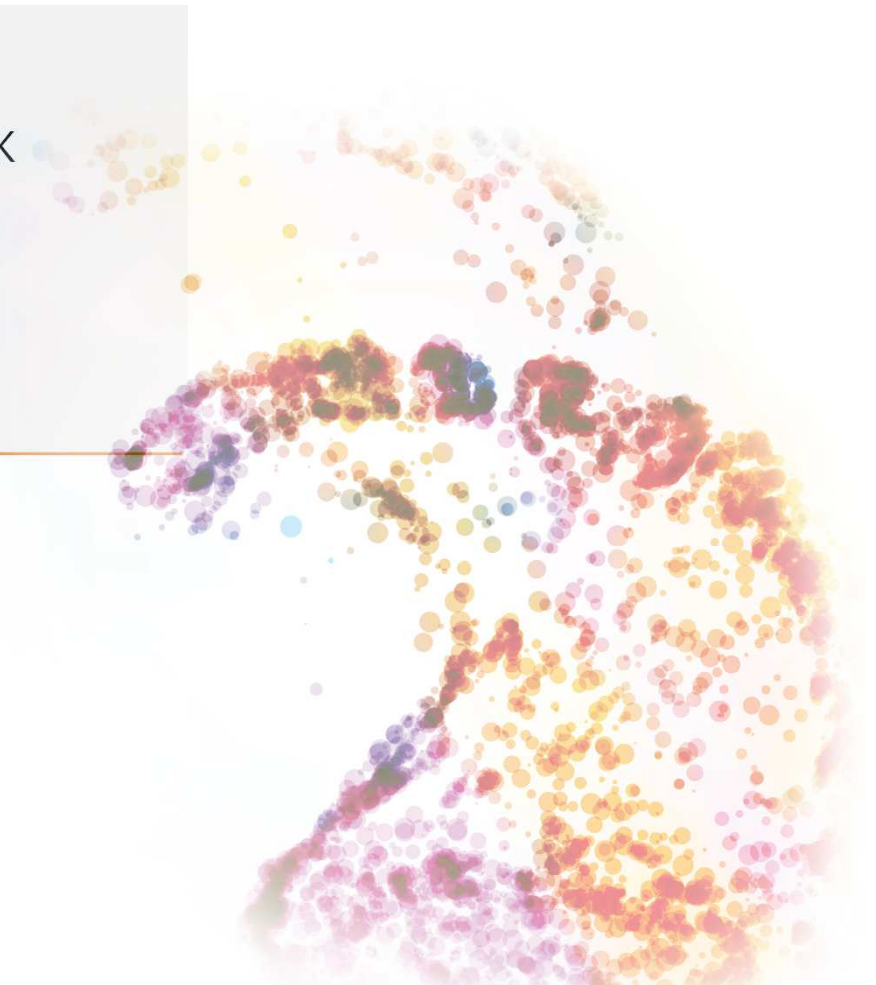
- Fluticasone PK comparable to Seretide® Accuhaler® PK
- Peak concentration of salmeterol higher, and did not satisfy BE criteria
- Safety profile similar to that of Seretide® Accuhaler®

Salmeterol – Fluticasone Dry Powder Inhaler

Next steps

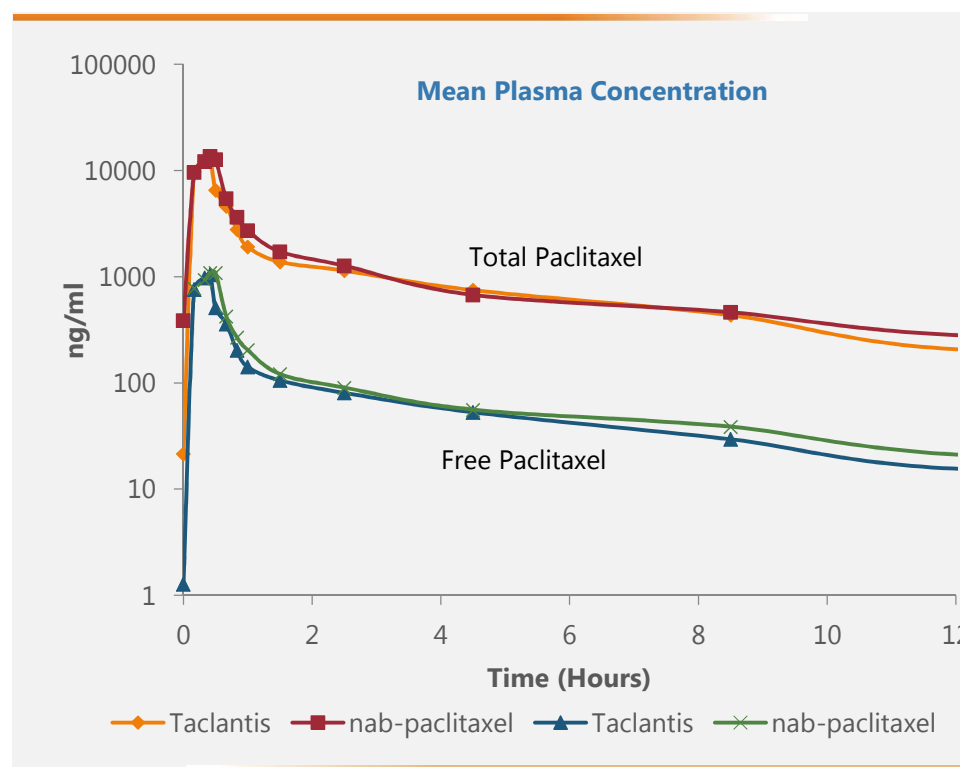


Based on PIF study, High dose and Low dose PK study data, SPARC is consulting EU regulatory agencies to understand path forward for approval of all 3 strengths



Novel formulation of paclitaxel using SPARC's proprietary Nanotecton™ platform technology

- Completed pilot BA/BE studies
 - Data suggest possibility of BE in a fully powered PK study
 - No unanticipated safety findings
- Initiated pivotal BE study in Q2FY18
 - 4 subjects randomized
- Planned NDA filing by Q3FY19

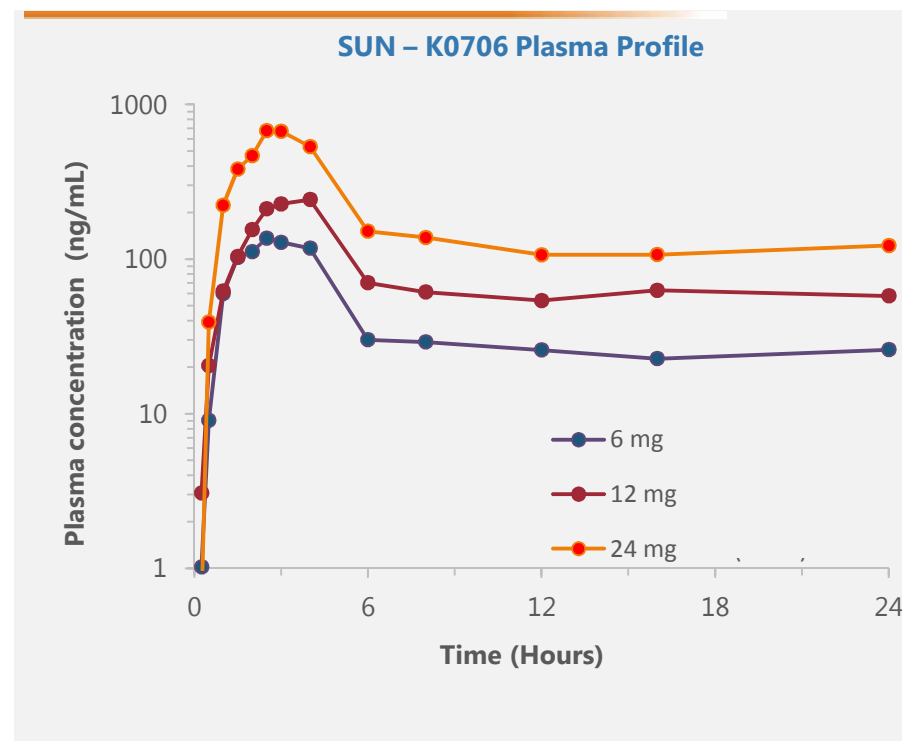


SUN – K0706 CML

Highly selective BCR–ABL Inhibitor



- Potent and orally bioavailable
- Effective against BCR-ABL and its mutants, including T315I mutation
- Completed Single Ascending Dose (SAD) study in healthy volunteers
 - Orally bioavailable
 - PK supports once-a-day dosing
 - Dose proportionality established
 - No food effect
 - Safe and well tolerated
- Initiated Multiple Ascending Dose (MAD) study in CML patients
 - 2 dose levels completed



SUN – K0706 CML

Development status update



- Plan to complete the MAD study by Q4FY18
- Initiation of pivotal efficacy study by Q2FY19

Brimonidine OD

Improving Glaucoma patient compliance and adherence



- Brimonidine is a commonly used second line drug to treat Glaucoma
- Treatment adherence with Brimonidine is highly variable*
- Patients on Brimonidine TID achieve significantly lower adherence rates*
- SPARC is developing a novel once-a-day formulation using proprietary TearAct™ Technology

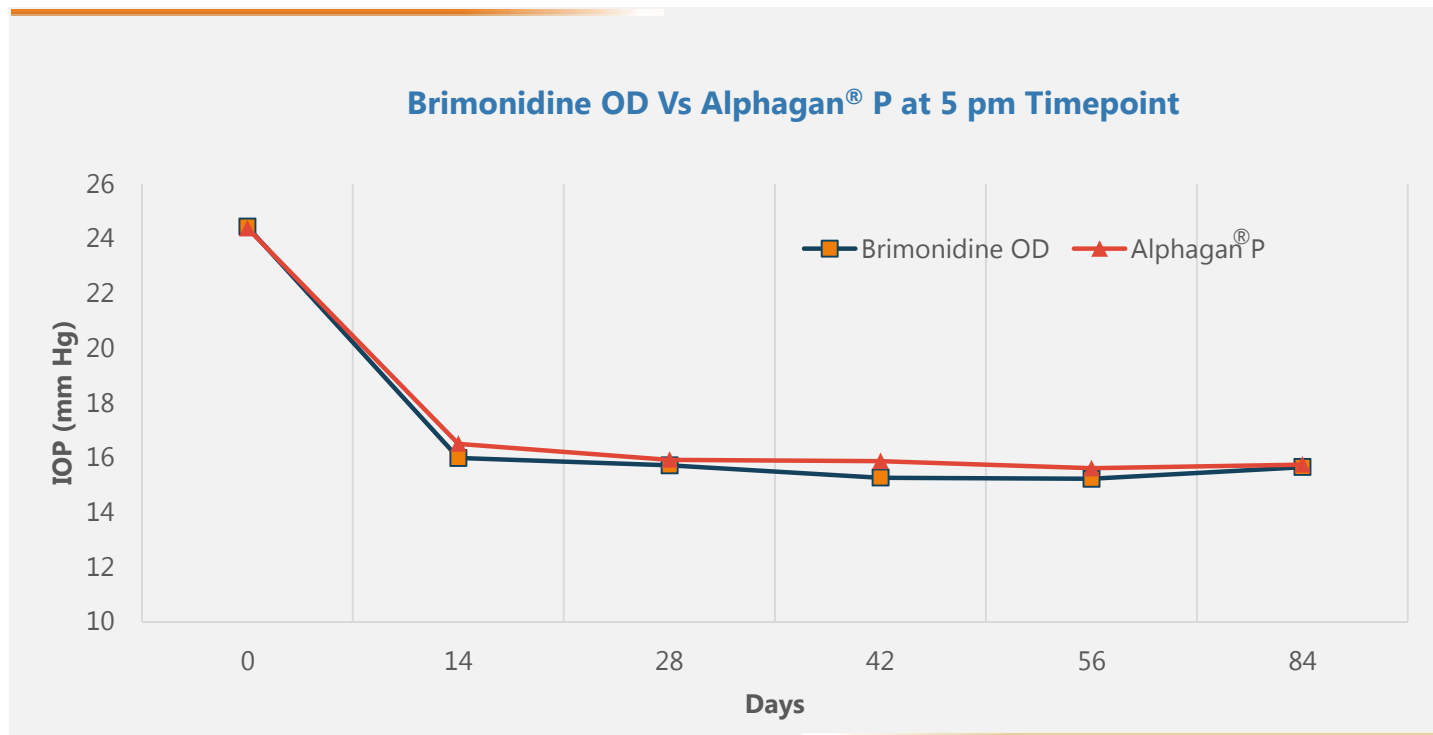


Brimonidine OD



Achieves similar IOP reduction as Alphagan® P TID

- Proof-of-concept established in Phase 2 study in 140 Glaucoma patients
- Met pre-specified clinical equivalence efficacy criteria compared to Alphagan® P TID at all time points
- No new adverse events reported



Brimonidine OD

Development status update



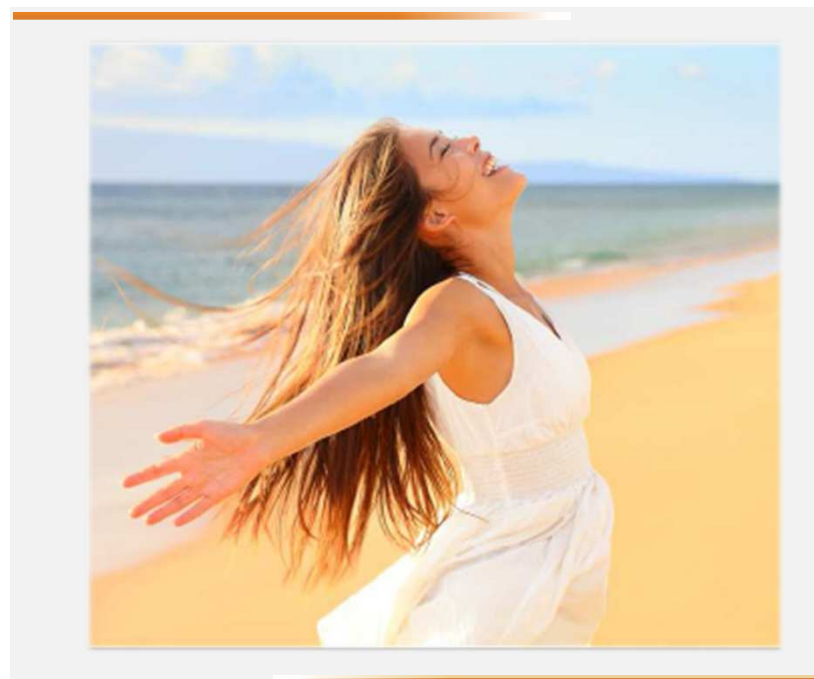
- EoP2 meeting with US FDA & IND filing by Q3FY18
- Phase 3 initiation by Q4FY18

SUN – 597 Topical

Development status update



- Novel topical steroid for steroid responsive dermatoses
- IND opened in USA
 - Phase 1 vasoconstrictor assay study completed
- Initiating pilot study in psoriasis patients, topline data expected by Q3FY18
- Phase 1 healthy volunteer safety/tolerability study planned in Q4FY18
- 30 day minipig toxicity study completed
- Outcome from the above studies will guide further clinical development



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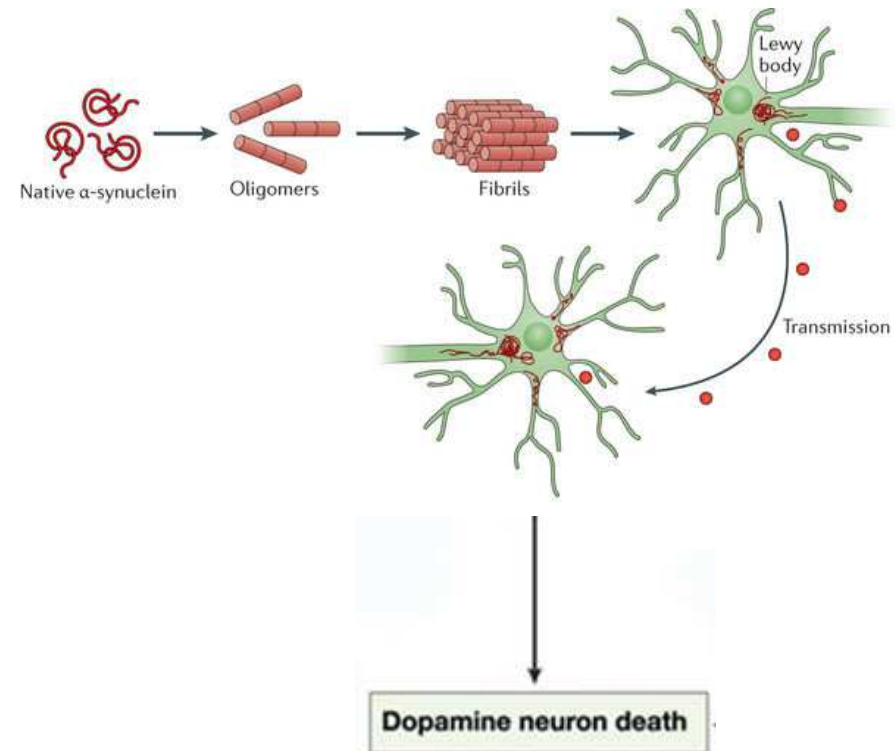
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Parkinson's Disease

Growing evidence of c-Abl kinase involvement

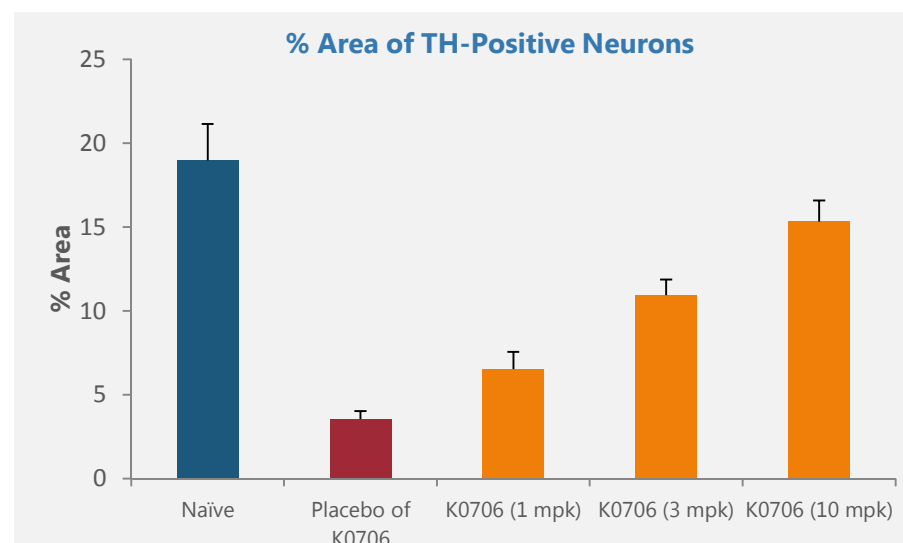
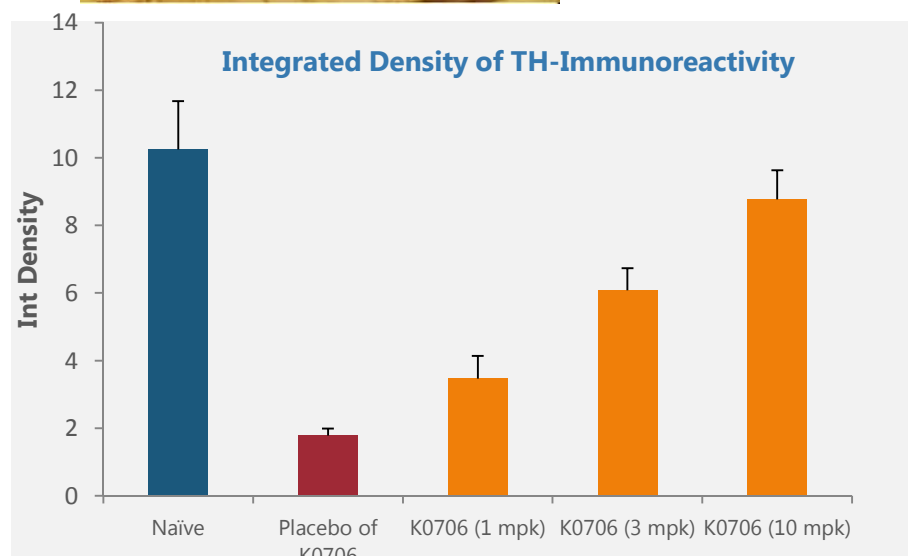
- 10 mn people worldwide living with Parkinson's Disease[^]
 - Currently available therapies provide symptomatic relief only
 - No disease modifying therapy available
- Expression and activation of c-Abl kinase is observed in neuronal cells overexpressing α -Synuclein
- Several proteins involved in proteosomal degradation and autophagy are substrates of activated c-Abl kinase
- c-Abl phosphorylation of α -Synuclein at tyrosine 39 enhances α -Synuclein aggregation



SUN – K0706 PD

Promising neuroprotective activity in mouse model of PD

Representative photomicrographs showing TH-immunoreactive neurons in SNPc



○ Crosses blood brain barrier

○ SUN – K0706 prevents MPTP induced degeneration of dopaminergic neurons in Substantia Nigra

SUN – K0706 PD

Initiated phase 1 study in Parkinson's Disease patients



Phase 1

- Assessment of PK, safety and tolerability in patients
- Study ongoing; 2 cohorts completed

Phase 2

- Proof of efficacy study in Parkinson's Disease patients to be initiated

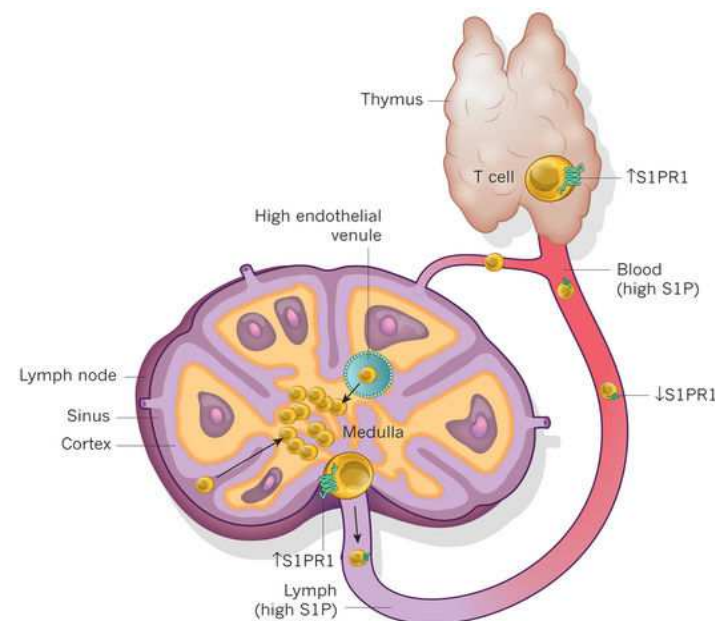


SCD – 044

Novel highly selective S1P Receptor 1 agonist for auto-immune disorders



- Project under collaboration with Bioprojet, France
- Fingolimod is the 1st in class S1P receptor agonist approved for Multiple Sclerosis
 - US\$ 3.1 bn global sales in 2016*
- Being non-selective modulator, Fingolimod is associated with serious cardiac side-effects
- SCD – 044 is highly selective for S1P receptor 1 (S1PR1) over S1PR3
- Higher selectivity for S1PR1 is expected to provide better cardiac safety profile



S1PR1 agonists	EC ₅₀ (nM)		
	S1PR1	S1PR3	S1PR5
SCD – 044	0.2	>10000	9
Fingolimod ¹	1.2	1.4	4.9

*Evaluatepharma; 1. JMC, 2005, 48,5373-77; Nature 510,58–67, June 2014

SCD – 044

Comparable pre-clinical efficacy to Fingolimod



- Achieves comparable lymphopenia, a marker of efficacy, across different species
- SCD – 044 is efficacious in animal models of autoimmune inflammation
- Desirable oral bioavailability and PK profile in animal species like mice, rat, dog and monkey
- No cardiac side effects observed in dog telemetry study

Drug	Lymphopenia		
	Rat, 0.3 mg/kg		Dog, 0.3 mg/kg
	24 Hrs	24 Hrs	48 Hrs
SCD – 044	78%	77%	77%
Fingolimod	72%	73%	75%

SCD – 044

Development status update



- Completed 13 week toxicity studies in rodents and primates
- Completed safety pharmacology and preclinical efficacy studies
- IMPD filed in Europe
- Phase 1 initiation by Q3FY18

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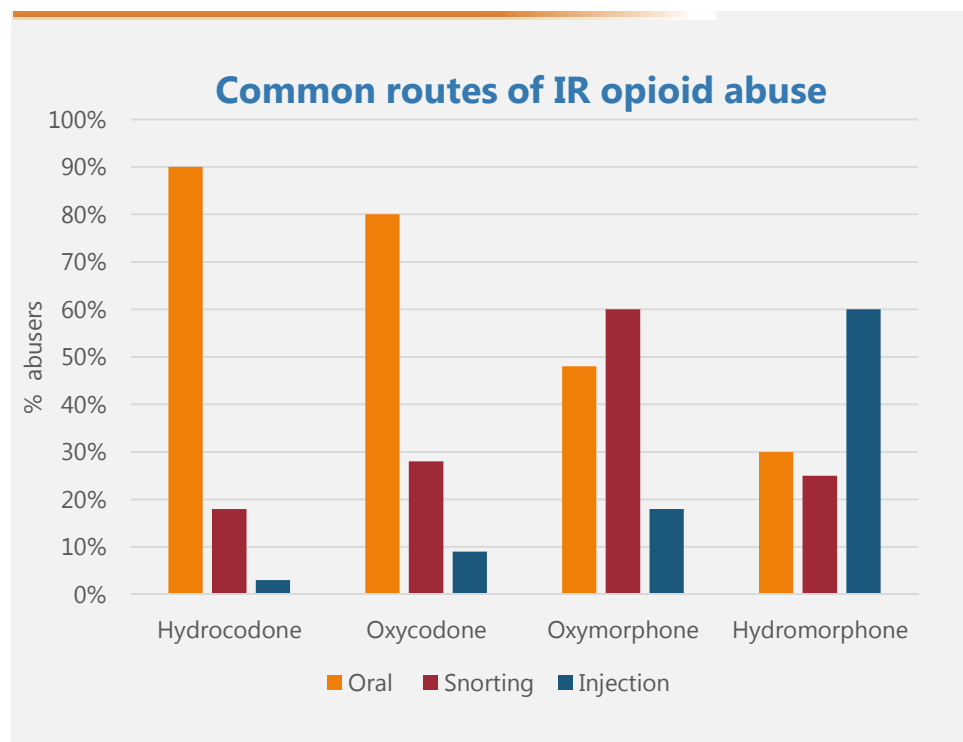
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Prescription Opioids Abuse

IR opioids are most vulnerable

- >20,000 deaths occurred in 2015 due to prescription opioid overdose*
- 66% of abusers prefer IR formulations#
 - Ease of manipulation drives preference for IR dosage forms
- Oral ingestion of multiple pills is the most common form of abuse^
- 10 ADFs approved by USFDA till date
 - None of the approved formulations have label for deterring oral multi-pill abuse

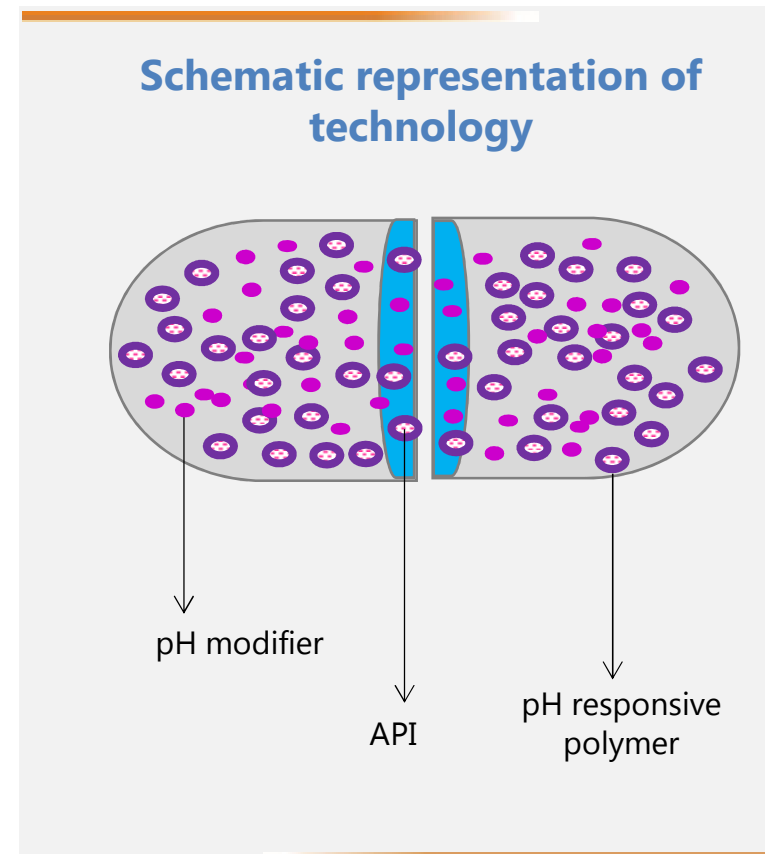


SDN – 021

Designed to deter multi-pill oral abuse

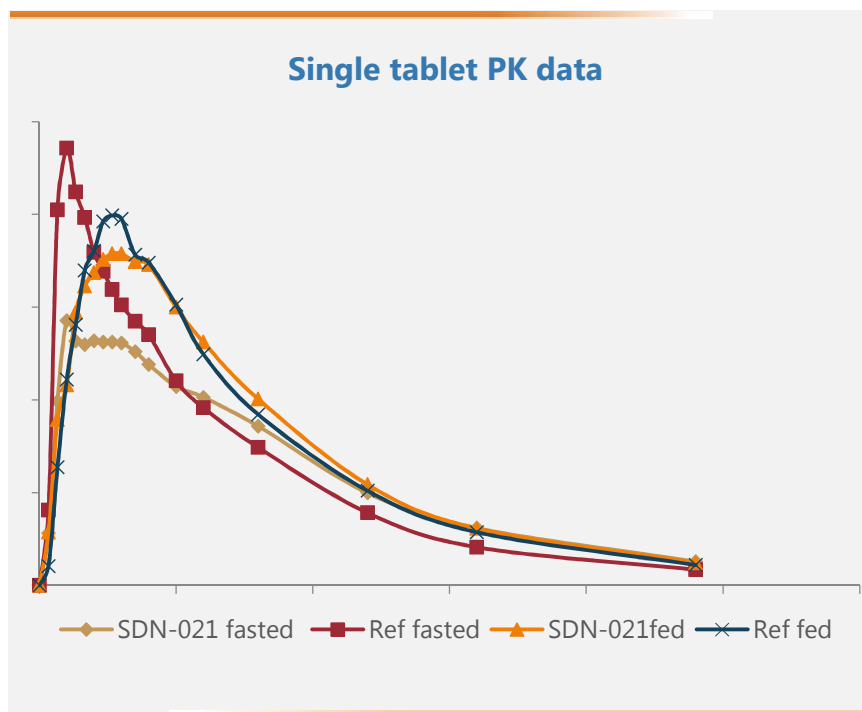


- Delivers clinically effective dose if used as prescribed
- Upon ingestion of multiple pills, the technology reduces peak drug levels and slows down the release
- Deprives abuser of the desired "high" with multiple pills
- Technology is also designed to deter abuse by other prevalent routes – injection and snorting
- Employs GRAS excipients

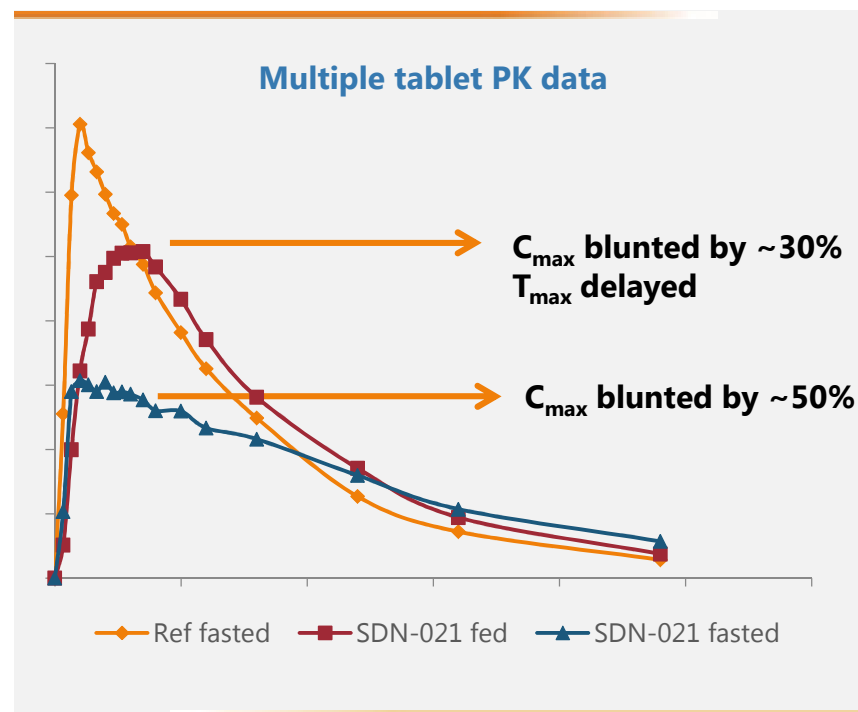


SDN – 021

Lead formulation demonstrated acceptable PK characteristics



- Fed state – Potential to meet BE in both AUC and C_{max}
- Fasted state – Potential to meet BE in AUC, however C_{max} was lower
- PK data appears to be adequate for efficacy in patients



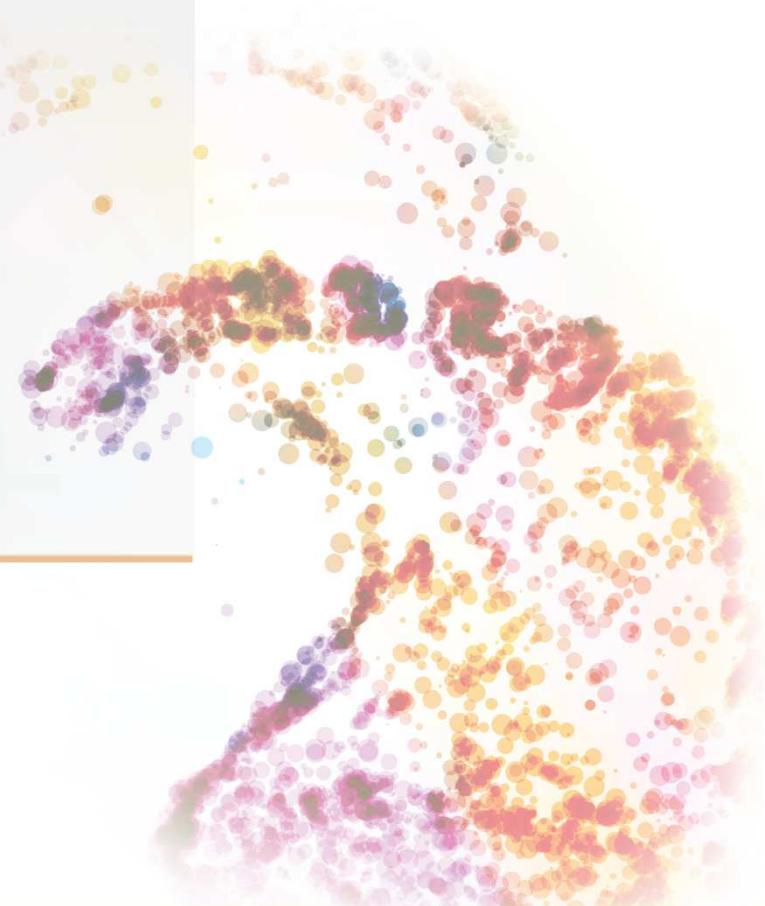
- Ingestion of multiple tablets resulted in optimal reduction in C_{max} and delay in T_{max}
- Manifests in potential optimal difference in human likability study

SDN – 021

Development status update



- *In-vitro* Category I Abuse Deterrence studies and Pilot Human Abuse Liability (HAL) studies planned in Q3FY18
- Consultation with USFDA planned to discuss registration pathway and Abuse Deterrence label for oral multi-pill abuse

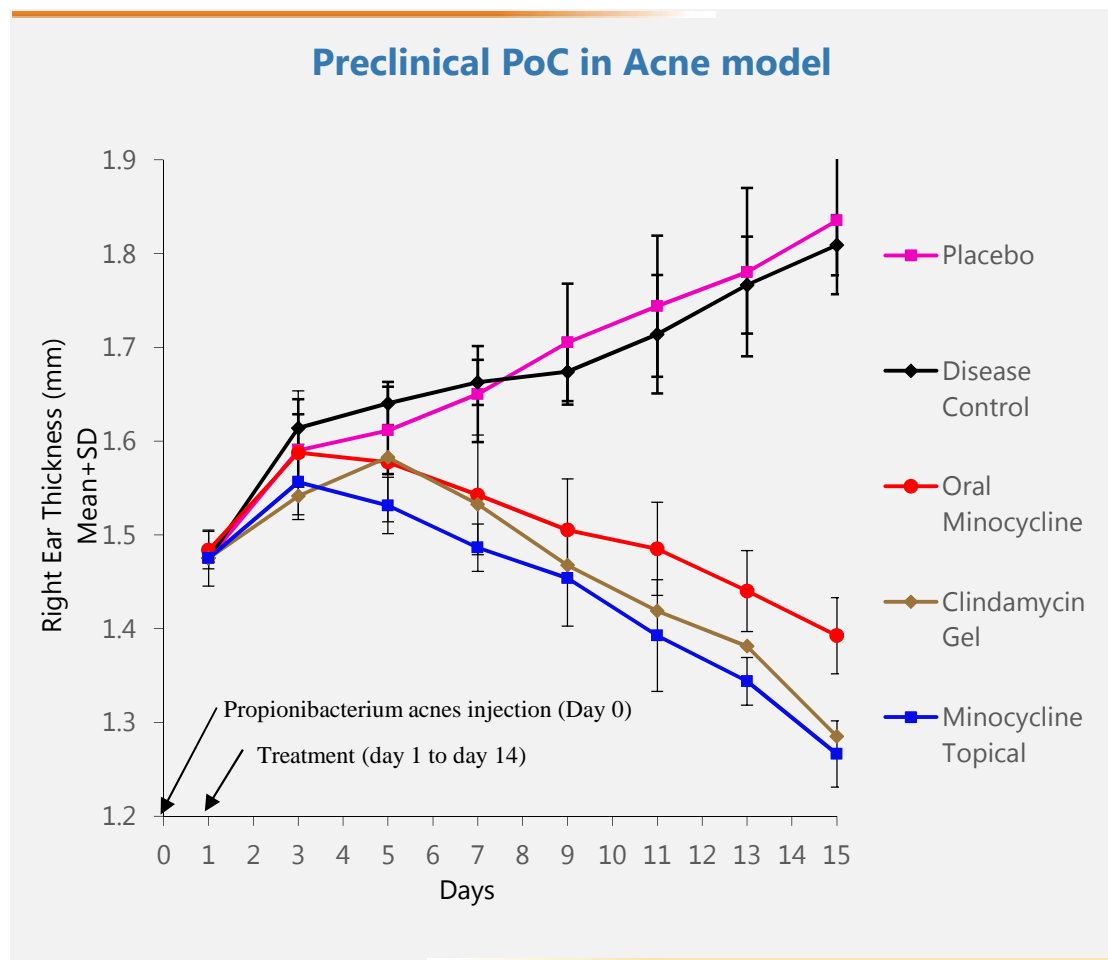


Minocycline Topical

Development status update



- Novel safer and efficacious formulation of minocycline for Acne
- Formulation optimized based on successful rabbit toxicity study outcome
- Minipig toxicity study ongoing
- Pre-IND meeting planned with USFDA by Q4FY18
- IND submission targeted in Q1FY19

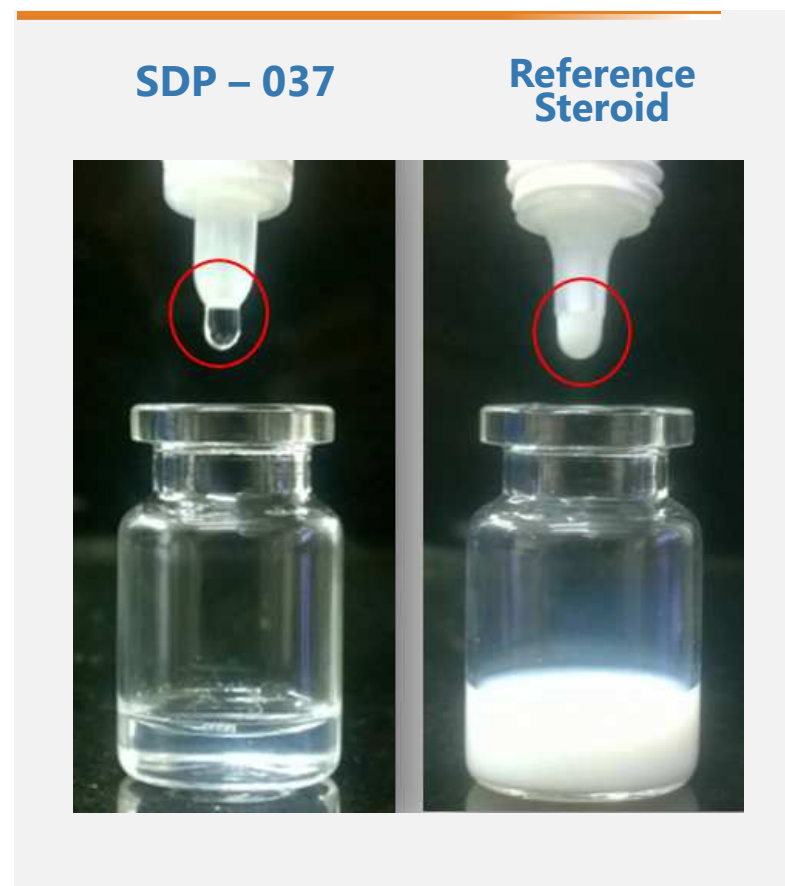


SDP – 037

Novel BID steroid for Ocular pain and inflammation



- Steroids are mainstay treatment for ocular pain & inflammation
 - US\$ 750 mn sales in USA*
- Currently approved steroid eye drops are administered 3 to 4 times per day
- Marketed eye drops have hazy/milky appearance which may cause blurring of vision upon instillation
- SPARC is developing novel formulation of an approved steroid
 - BID dosing
 - Clear/transparent appearance

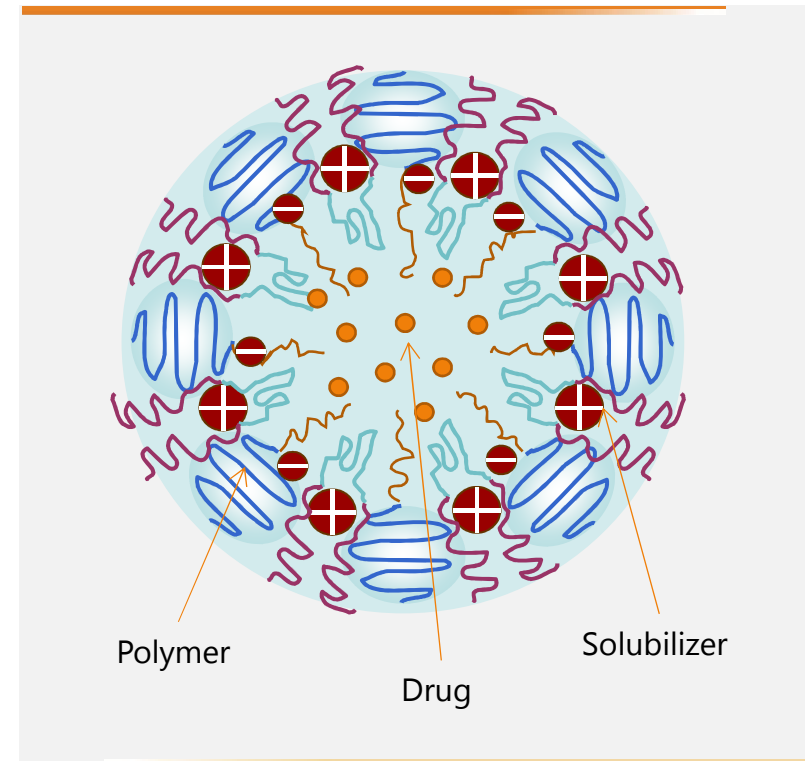


SDP – 037

Designed with novel Micellar Technology



- Uses proprietary composition of non-ionic, cationic and anionic solubilizers to produce unique micelles
- Solubilization of steroid provides clear colorless appearance
- Polymeric stabilizer provides longer retention and bio-adhesion
- Helps retain efficacy at reduced dosing frequency & lower drug concentrations
- Patents filed

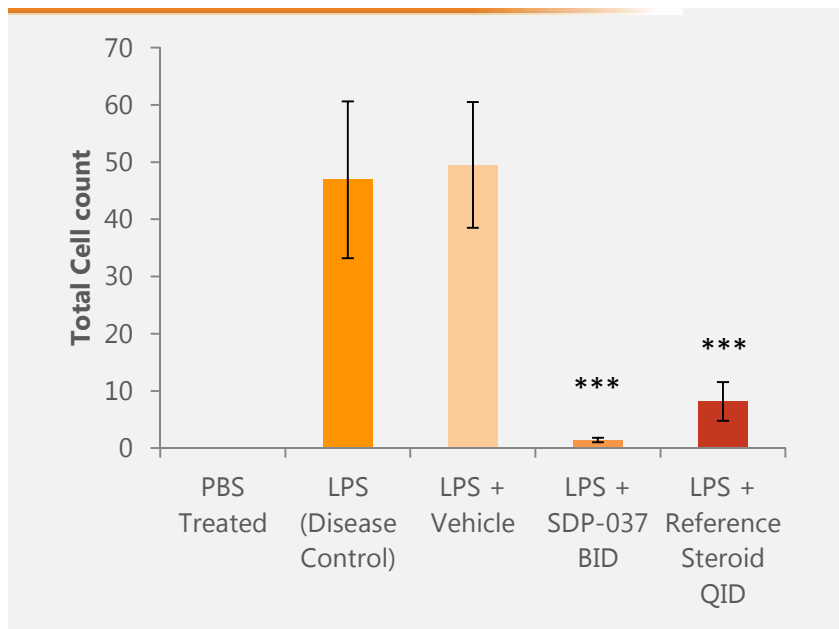


SDP – 037

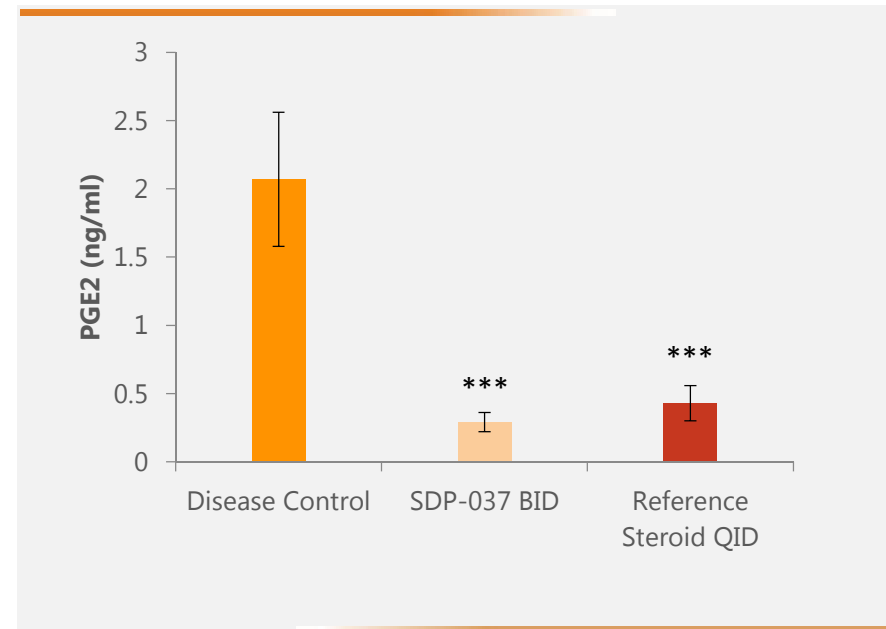
Comparable pre-clinical efficacy at BID dosing and lower drug concentration



Efficacy of SDP-037 vs. Reference Steroid in rabbit model of acute uveitis



Efficacy of SDP-037 vs. Reference Steroid in rabbit model of paracentesis



Data were analyzed using one way ANOVA followed by Dunnett's multiple comparison test versus Disease Control, ***= p<0.001 .

SDP – 037

Development status update



- Pre-IND meeting with USFDA completed
- IND submission by Q4FY18
- Phase 3 pivotal study initiation by Q1FY19

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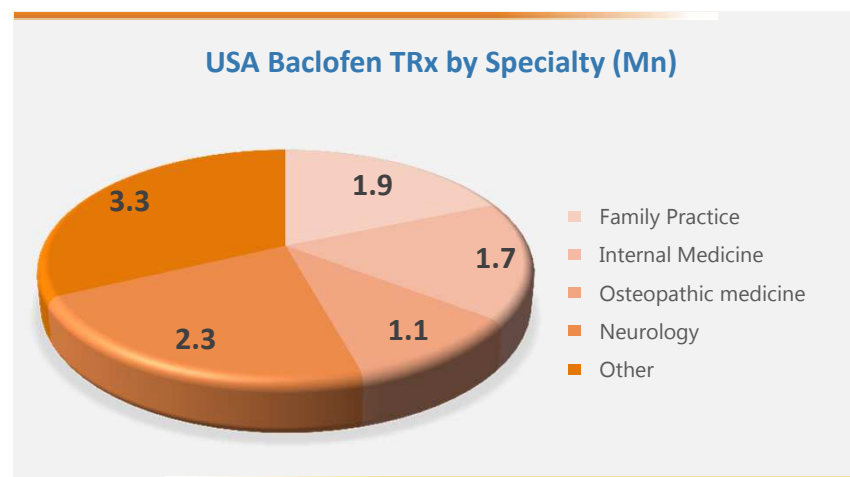
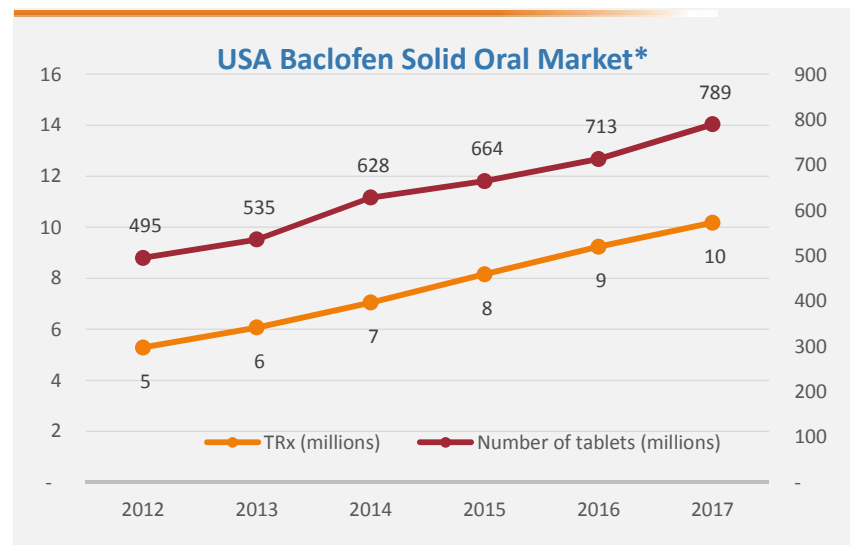
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Baclofen GRS

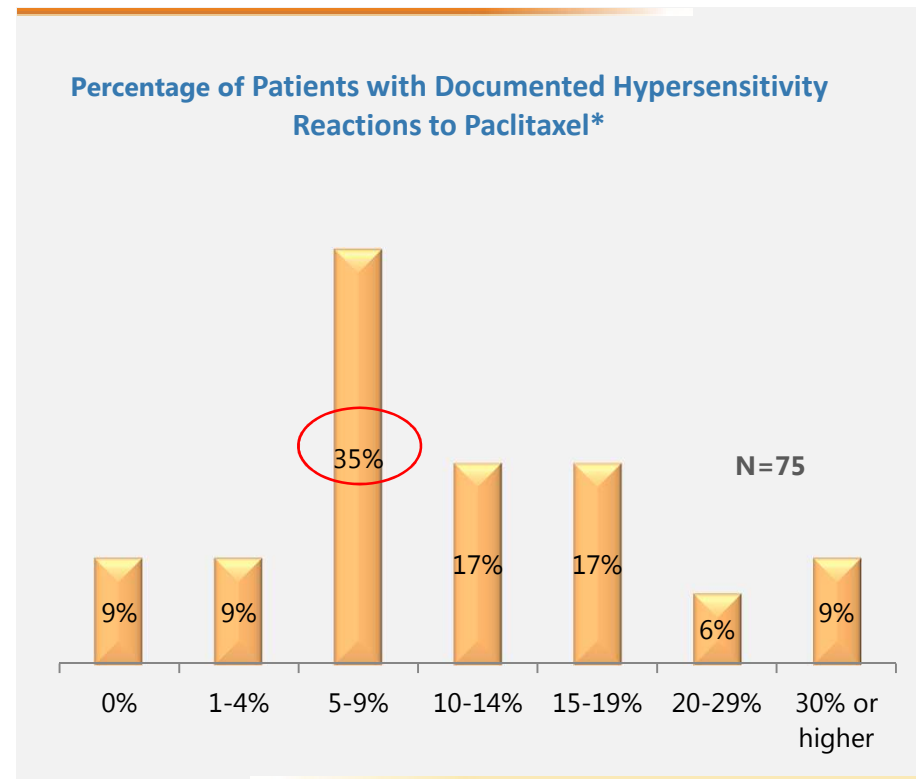


Significant commercial opportunity for once-a-day formulation

- Majority of physicians believe that steady blood levels and once-a-day dosing are key benefits over IR Baclofen[^]
- IR Baclofen highly genericised; unit volume in USA growing at 11%
- Prescription volume at 10 mn, dispensed by wide spectrum of specialties
- 25% - 35% of prescription market is potentially addressable
- Estimated USA peak sales potential ~US\$100 mn



- Cremophor® based paclitaxel formulations are associated with hypersensitivity reactions
- ~12% of patients have documented hypersensitivity reactions*
- Taclantis™ eliminates the need of pre-medication with corticosteroids and anti-histamines
- No significant hypersensitivity reactions observed in clinical studies with Taclantis™

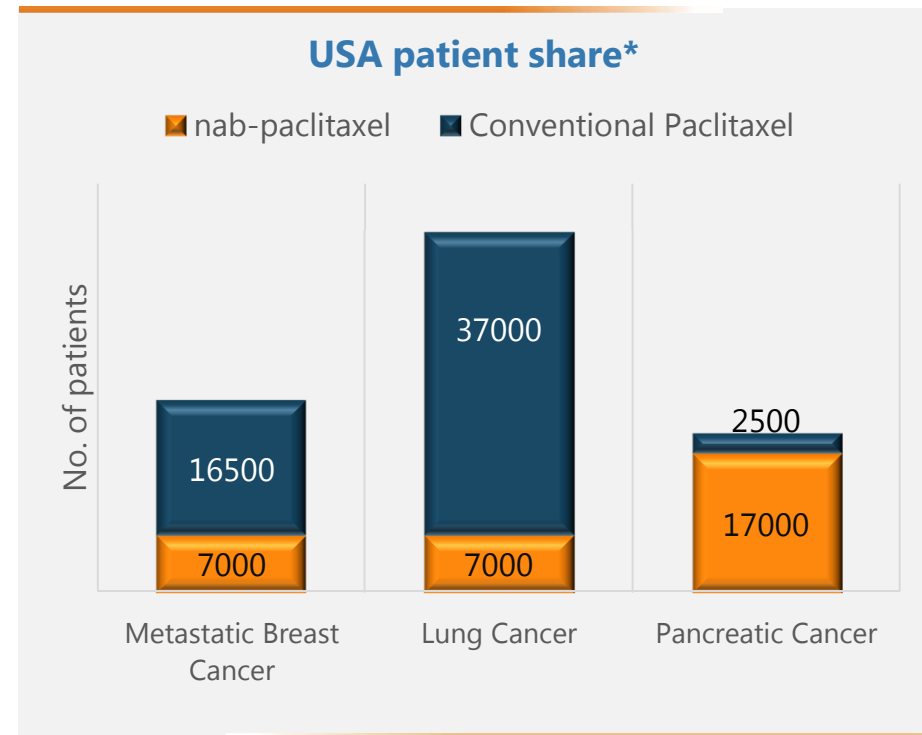


Taclantis™

Market Opportunity



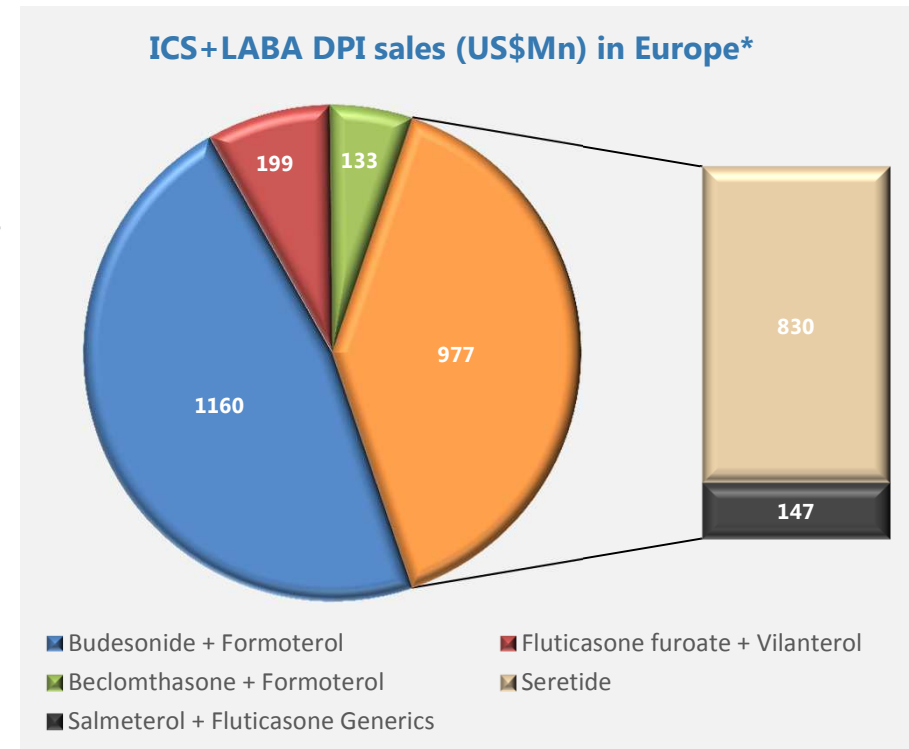
- Overall paclitaxel volume sales stagnated over last 2 years
 - Increasing penetration of novel agents may limit the use of paclitaxel
- ~ 65% paclitaxel treated patients prescribed Cremophor® based formulation*
- Significant opportunity for conversion to novel formulations like Taclantis™



Salmeterol – Fluticasone Dry Powder Inhaler

ICS/LABA DPI market dynamics in Europe

- Total ICS/LABA Dry Powder Inhaler market in Europe is estimated to be ~ US\$ 2.5 bn*
- Seretide® Accuhaler® has market share of 34% in ICS/LABA market
- New once-a-day device products are rapidly gaining market share
- Seretide® Accuhaler® generics have so far achieved limited penetration*
- Significant price erosion of Seretide® Accuhaler®
- Market may see additional generics

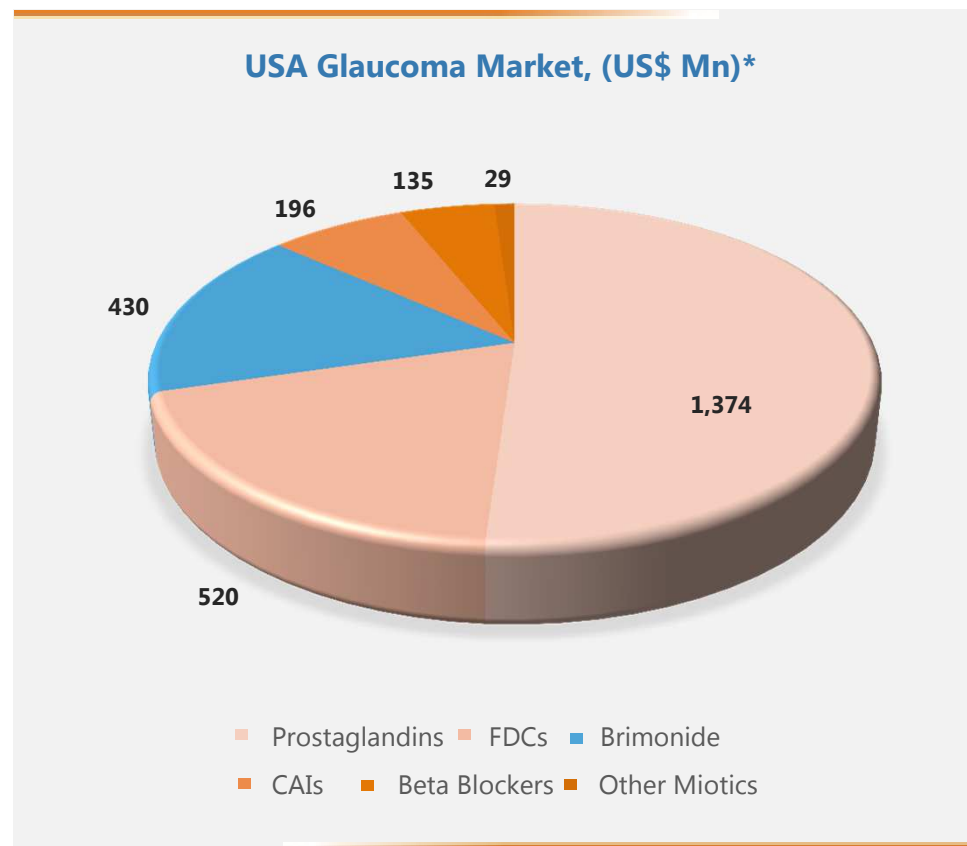


Brimonidine OD

USA Glaucoma market – Healthy growth trend



- Over 2.7 mn glaucoma patients in the USA; expected to reach 4.3 mn by 2030**
- Glaucoma market in USA estimated at US\$ 2.7 bn with 35 mn prescriptions dispensed in last year*
- Rx volume growth of 4.1% CAGR over 2012-17
- Brimonidine is the highest prescribed antiglaucoma drug after Prostaglandins

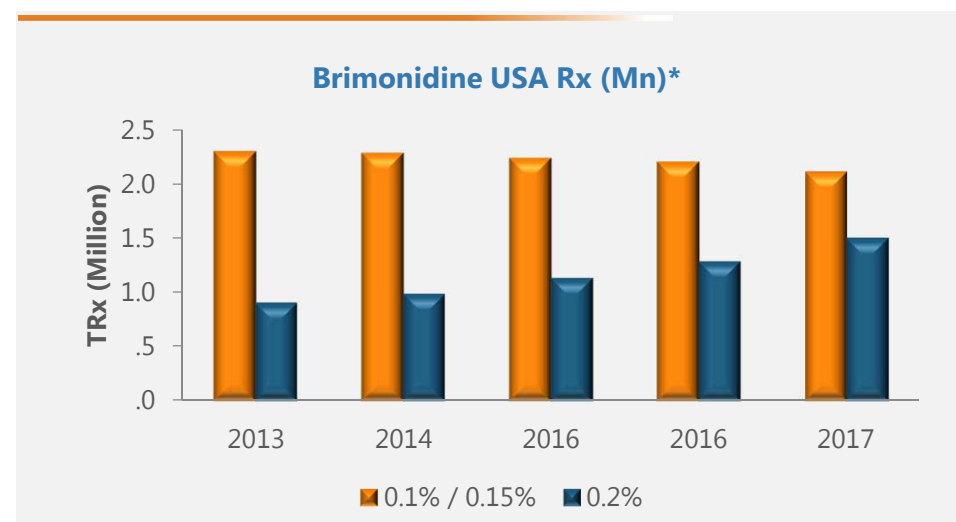
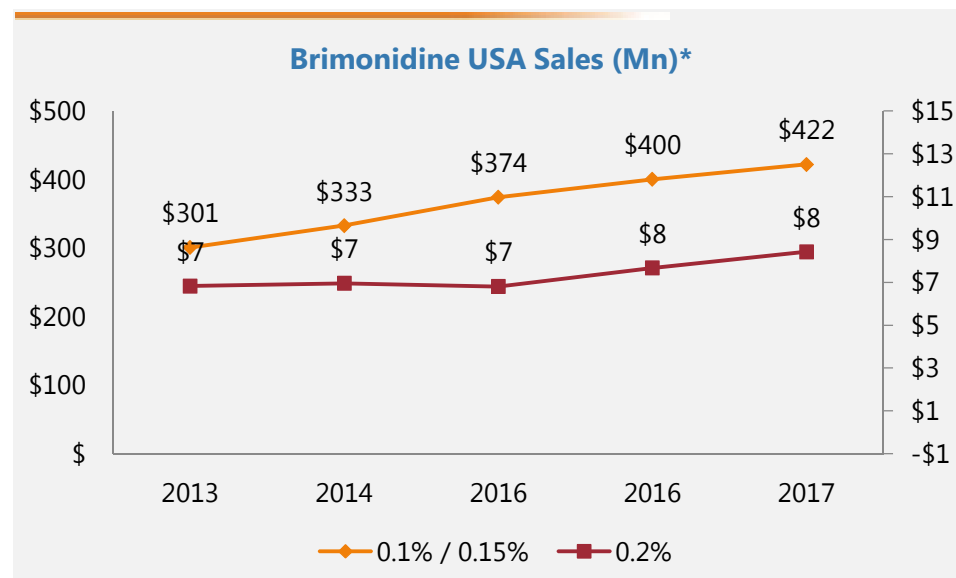


Brimonidine OD



Market acceptance of improved Brimonidine products

- Brimonidine initially approved as Brimonidine 0.2% eye drops
- Tolerability issues with 0.2% strength led to development of 0.15% and 0.1% products
- Brimonidine 0.15% and 0.1% continue to dominate market in both value and volumes inspite of genericization of Brimonidine 0.2%
- Differentiated once-a-day Brimonidine formulation expected to take meaningful market share

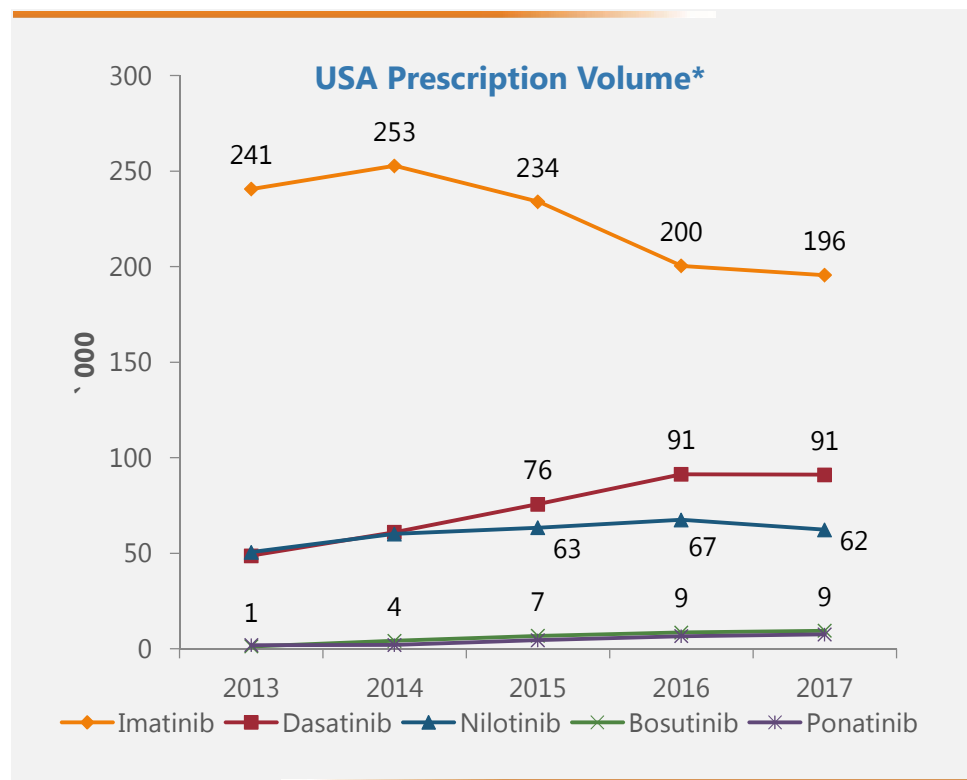


SUN – K0706 CML



Addressing high unmet need in treatment resistant CML

- Estimated 50,000 patients are living with CML in USA[^]
- ~15% patients discontinue 2nd line therapy due to adverse events[#]
- Limited treatment options for patients who fail two lines of treatment
- Low physician satisfaction for available 3rd line and beyond treatment[#]
- SUN – K0706 has demonstrated efficacy and safety in treatment resistant CML preclinical models and toxicology studies



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Financial Summary



(INR Mn)	FY17	FY16	FY15	FY14	FY13
Total Income	1,946	1,642	1,588	1,770	889
Total Expenses	3,149	2,342	1,983	1,427	1,114
Profit / (Loss) after tax	(1,203)	(700)	(395)	303	(225)

Liquidity Status

- Cash and equivalents INR 282 mn as on 30th June '17
- Delay in commercialization of Xelpros™ & Elepsia™ XR
- Higher working capital need due to GST

Financial Summary



- Expected cash outflows
 - Increased number of clinical programs
 - Higher operating expenses
 - Acquisition & refurbishing cost of new facility at Savli

- Expected cash inflows
 - Raised INR 5,000 Mn through Preferential Issue of Warrants (25% received)
 - Out-licensing of Baclofen GRS if clinical studies outcome is positive

Agenda



1 | **SPARC Strategy & Upcoming Milestones**
Anil Raghavan – CEO

2 | **Key Clinical Programs**
SiuLong Yao – Sr. V.P. Clinical Development & Operations

3 | **Drug Discovery Programs**
Nitin Damle – Sr. V.P. Discovery Biology & Pre-clinical R&D

4 | **Delivery System Innovations**
Yashoraj Zala – V.P. Formulation Development
Ajay Khopade – V.P. Formulation Development

5 | **Market Opportunity – Key Programs**
Narendra Lakkad – V.P. Business Development

6 | **Financial Update**
Chetan Rajpara – CFO

7 | **Q&A**

R&D Pipeline





For updates and specific queries,
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