

Investor Update on R&D Pipeline

February 26, 2014



**SUN PHARMA
ADVANCED RESEARCH
COMPANY LTD.**



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FY 2013 -14 Major Milestones

- PICN
 - Marketing approval in India
 - EOP2 meeting with USFDA
 - Grant of US Patent
- Latanoprost “BAK free” Ophthalmic Solution - First NDA filing in US based on Phase III clinical program
- Latanoprost and Timolol Ophthalmic Solution marketing approval in India
- SUN -597 DPI first in human study initiated in UK
- SUN - 597 Nasal – US IND acceptance; initiated Phase II study

Key Therapy Area and Research Programs

OPHTHALMOLOGY

Swollen Micelle Microemulsion (SMM)
Gel Free Reservoir Technology (GFR)

ONCOLOGY

Nanotecton™
Liposomal Drug Delivery
Biodegradable depot
Tyrosine kinase inhibitor

CNS

GRID™
Wrap Matrix™

RESPIRATORY

DPI
Soft steroid
LTD₄ antagonist

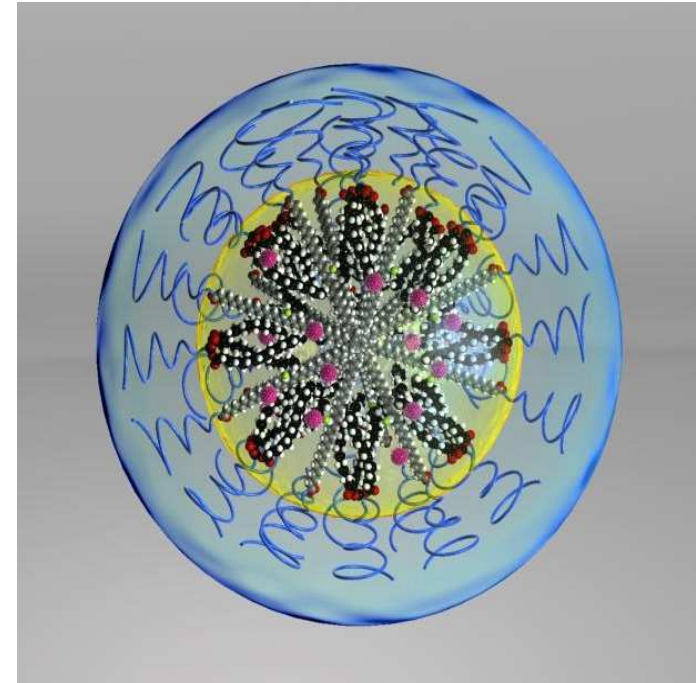
OPHTHALMOLOGY

Latanoprost

Latanoprost
+
Timolol

Latanoprost “BAK Free” Ophthalmic Solution

- Reduced risk of ocular surface damage on chronic use
- Potentially beneficial in chronic glaucoma patients with dry eyes
- Stable at room temperature; ease of storage and transportation in distribution channels



“Swollen Micelle Microemulsion”

Latanoprost “BAK Free” - Glaucoma opportunity

- Glaucoma is largest segment in ophthalmic market. 2.2 million patients are diagnosed in US ; estimated to reach 3 million by 2020; 74 % are Open Angle Glaucoma (OAG) ¹
- 48%-59% of OAG patients show concurrent ocular surface disease (OSD) , 27% show severe OSD (dry eye)²
- Relationship between BAK use and OSD well established, 2 fold odds³
- Current state – co prescription of artificial tears/lubricating eye drops

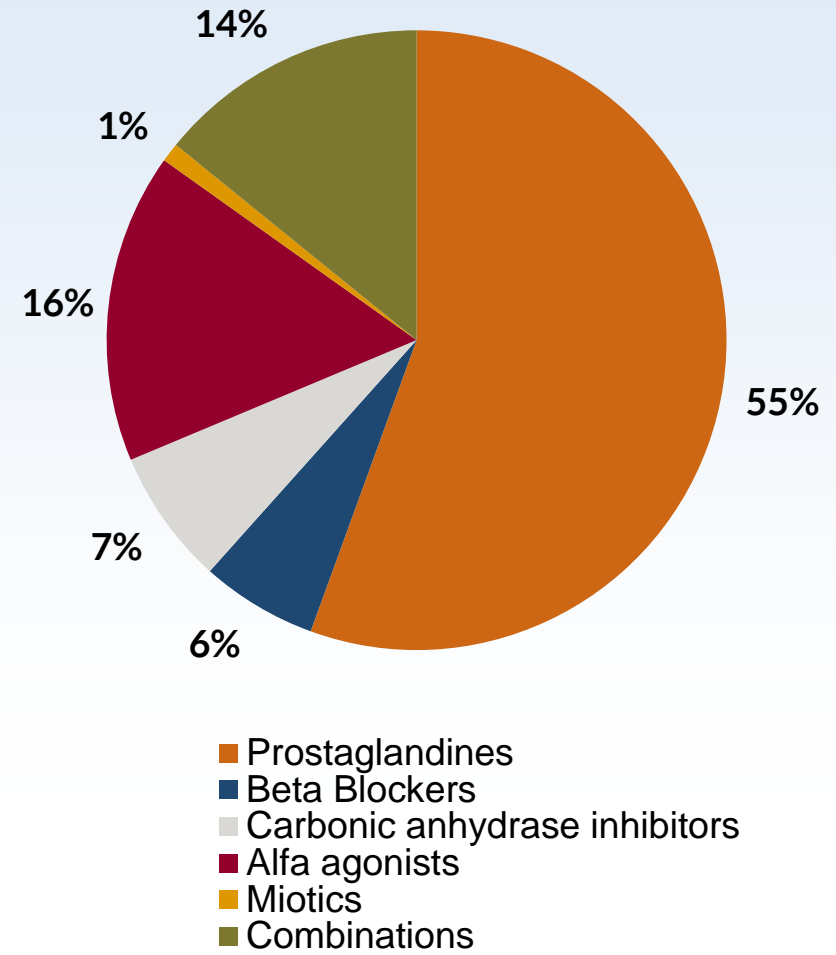


Latanoprost “BAK Free” US Commercial opportunity

Glaucoma Market

- Glaucoma products sales in US at ~ US\$2 Bn
- Prostaglandin products constitute 55% of sales
- Prostaglandins market was growing at 6% in 2013

US Glaucoma Market - 2013
(US\$2 Bn)

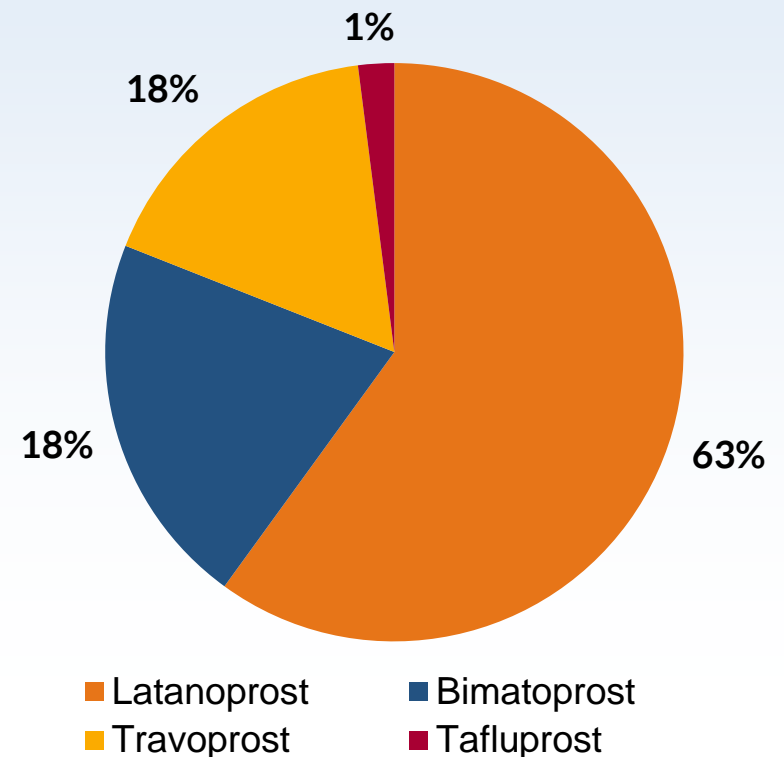


Latanoprost “BAK Free” US Commercial opportunity

Latanoprost “BAK Free” market potential

- Latanoprost is the largest selling PG with 63% volume share
- Market access studies suggest that 10% - 16% patients on Xalatan® and other BAK containing products develop Ocular Surface Disease symptoms
- Estimated potential patient population for SPARC’s Latanoprost
 - ~ 15 % patients on Xalatan® and its generics and new patients with high risk of developing OSD

US Prostaglandin Market - 2013
(22 Mn. Units)



Regulatory status update

US -505(b)(2) route

- NDA Filed Q4 FY 2013-14
- Evaluating various options for commercialization

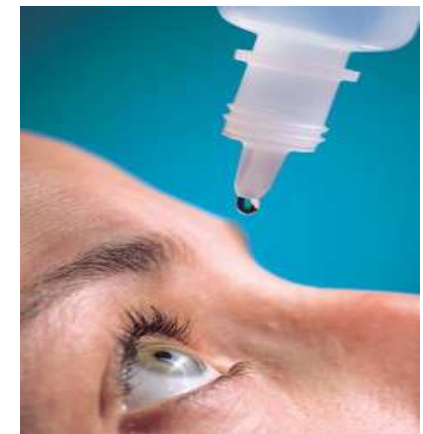
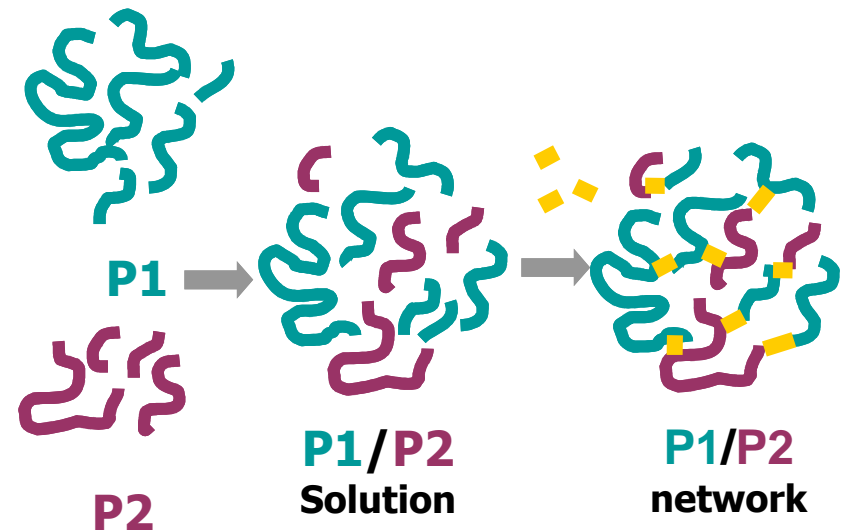
ROW

- 4 EM filing completed ; 5 more markets planned in FY 2014-15



Latanoprost and Timolol OD Ophthalmic Solution

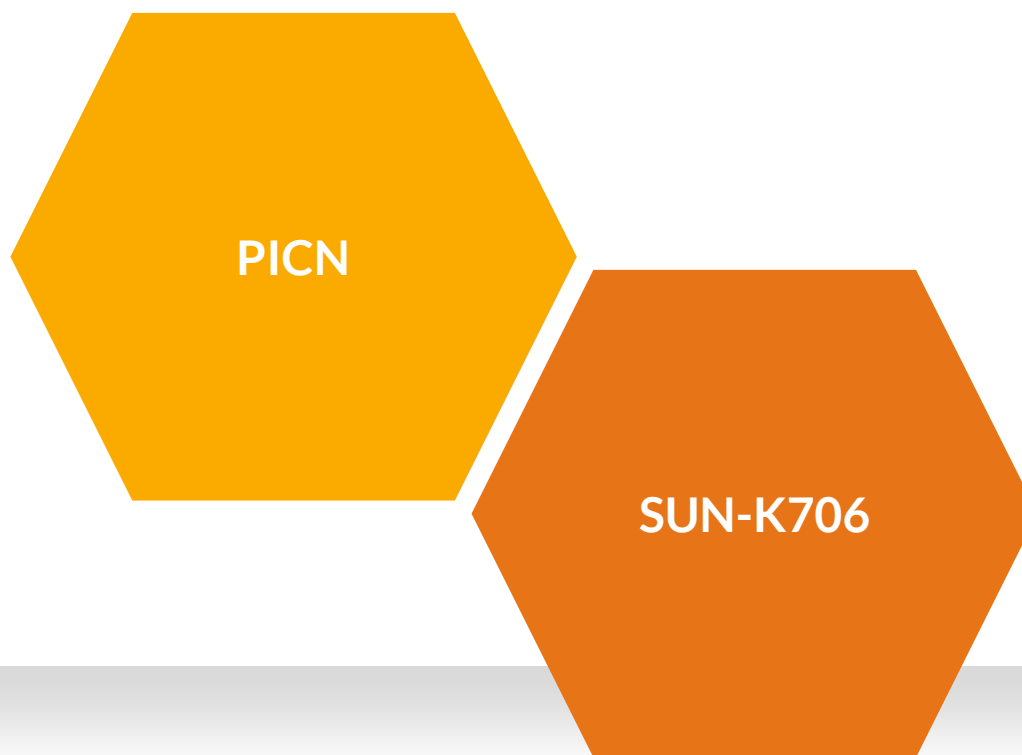
- Combination of essential elements of the SMM into GFR platform
- Once a day dosing
- Product with characteristics similar to natural tears
- Storage at room temperature
- Efficacy of FDC met NI criteria of +/- 1.5 mm Hg with concomitant therapy of Xalatan[®] + Timoptic[®] BID



Regulatory status update

- Launched in India : Q4 FY 2013-14
- Select ROW markets filing planned in FY 2014 -15
- Advice obtained from regulatory consultants for potential EU filing; Evaluating commercial potential for EU

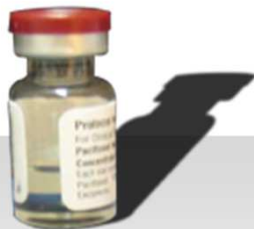
ONCOLOGY



Paclitaxel Injection Concentrate for Nanodispersion (PICN)

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

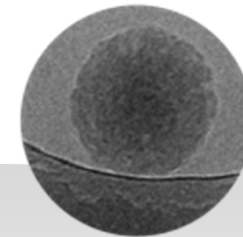
- Cremophor® and Albumin free formulation
- 30 min infusion
- No standard paclitaxel pre-medications required
- Allows higher dose than TAXOL®



PICN as Supplied



PICN as admixture



Electron microscope
image of nano particle

50 nm – 150 nm in size

FDA feedback for regulatory pathway in US

SPARC completed End of Phase II meeting with FDA in December 2013

- Single Phase III clinical study required for approval in metastatic breast cancer
-

Next Steps

- Submit the Phase III study protocol to FDA by Q2 FY 2014-15
- Initiate study in Q3 FY 2014-15

Update on ongoing phase I studies

In Phase I studies, clinical benefit was observed in various tumor types with patients exposed to several lines of treatment

- Biliary carcinoma
- Ovarian cancer
- Cervical cancer
- Melanoma
- Anal canal cancer
- Bladder cancer

MTD reached in the ongoing Phase I clinical study of PICN with Carboplatin

Next steps

- Planning to initiate Phase II studies in 2 indications in FY 2014-15

PICN – US Commercial opportunity in breast cancer

- Paclitaxel and ABRAXANE® are not approved in weekly dosing schedule for breast cancer
- As per market research
 - 85%- 90% of Paclitaxel and ABRAXANE® are used in weekly dosing schedule
 - Estimated 30,000 breast cancer patients are on Paclitaxel therapy every year
 - Of which 12,000 patients are with metastatic breast cancer
 - Additionally 9000 metastatic breast cancer patients are treated with ABRAXANE®
- At similar efficacy and safety in weekly dosing , PICN could address this patient population

Regulatory status update

US -505(b)(2) route

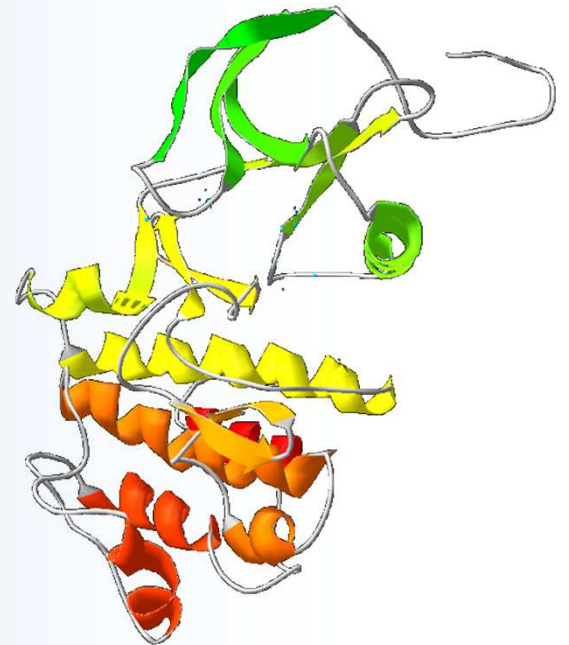
- Received FDA guidance for registration of PICN in metastatic breast cancer indication in weekly dosing regimen
- Phase III trial planned Q3 FY 2014-15

India

- Obtained marketing approval for India in Q4 FY 2013-14
- Expected launch in Q1 FY 2014-15

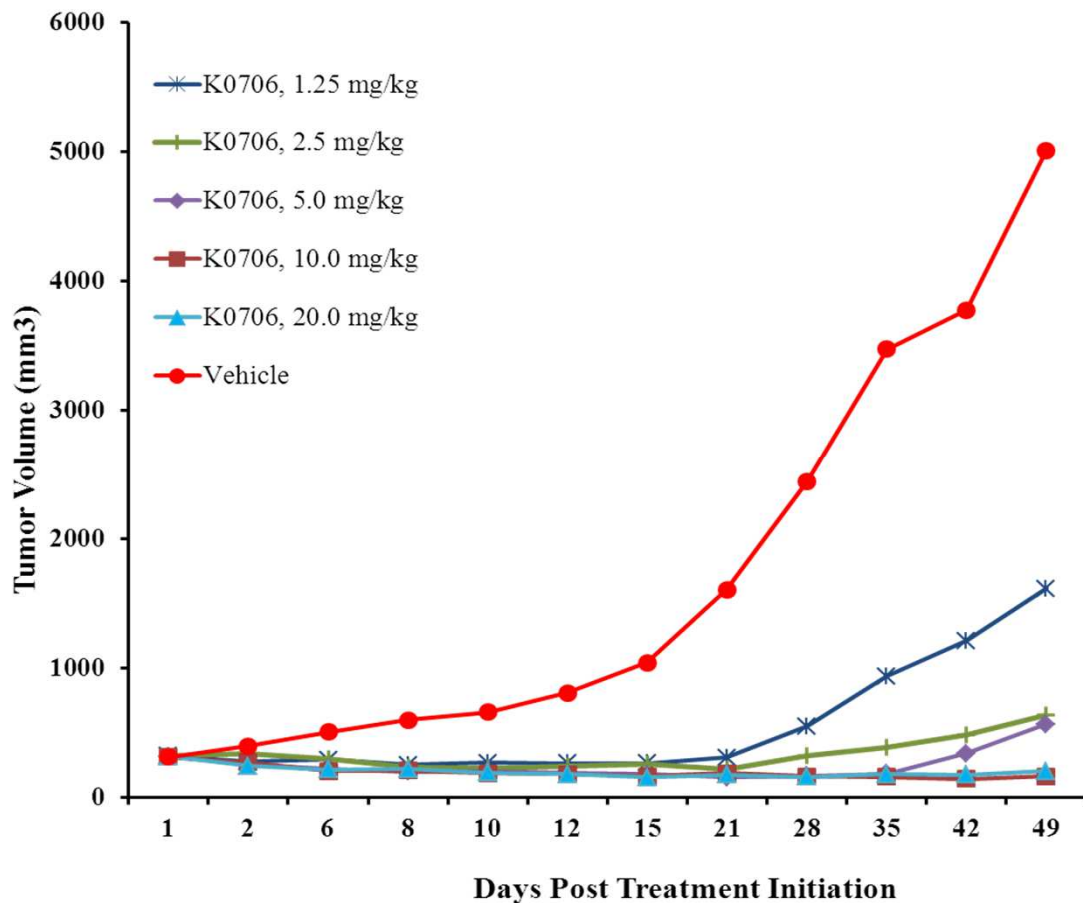
SUN-K706 Excellent preclinical profile

- Potent and highly selective Bcr-Abl Tyrosine Kinase Inhibitor
- Significantly inhibits the key Imatinib resistant mutants, including the T315I mutation
- Unlike Ponatinib, the only approved TKI for T315I mutation, SUN-K706 is not a pan Bcr-Abl kinase inhibitor
- Being selective, SUN-K706 is less likely to have off-target side effects
- Suitable formulation for clinical studies is optimized



Bcr-Abl Kinase

SUN-K706 In vivo efficacy in tumor xenograft model with optimized formulation



SUN-K706 formulation shows dose dependent anti-tumor activity in tumor xenograft in mice model

SUN-K706 Excellent *in vivo* safety profile

Low potential for cardiac side effects

- No significant effect seen on heart rate, arterial blood pressure and “rate corrected” QT intervals in telemetered Beagle dogs
-

Low potential for hemostasis

- Unlike Dasatinib therapy, where thrombocytopenia and platelet function have been implicated, SUN-K706 caused less bleeding in mice indicating low potential for such side effects

SUN-K706 Future development plan

- Complete Safety pharmacology studies by Q2 FY 2014- 15
- Complete Toxicity studies for IND by Q3 FY 2014-15
- File IND in Q4 FY 2014-15



Levetiracetam

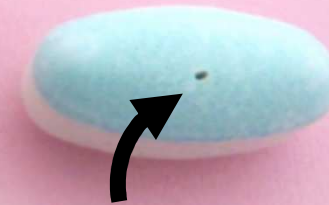
Venlafaxine

Baclofen



Levetiracetam ER 1000mg / 1500mg

- NDA for Levetiracetam ER was filed in US in Q1 FY 2012-13
- SPARC received complete response letter in May 2013
- Interaction with USFDA was completed and FDA is in agreement with SPARC's proposal to conduct 1 additional pharmacokinetic study
- Response to FDA planned by Q2 FY 2014-15
- Composition and dose specific patents granted in US with expiry up to 2028



Wrap Matrix™

Use of Laser drill to achieve a controlled release with minimal excipients

Levetiracetam ER - US Commercial opportunity

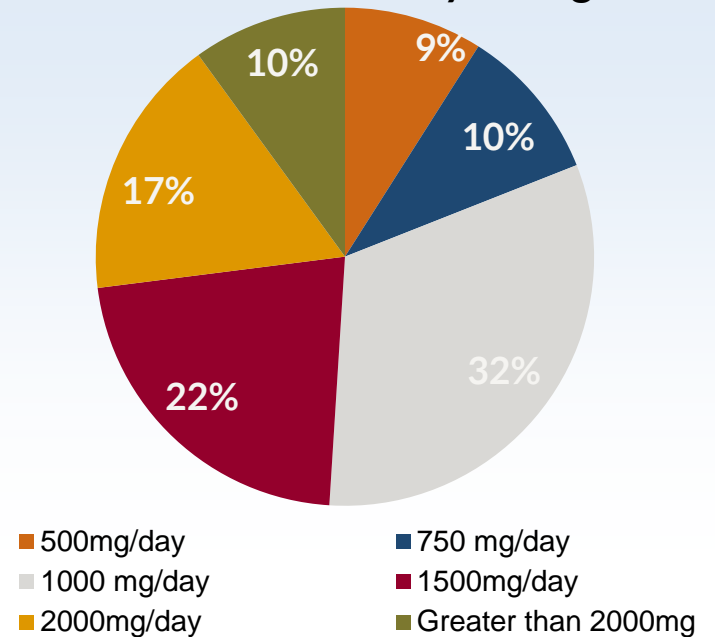
Market access studies in US

- Epilepsy patients in US: Pill burden remains high (>55%) at >6 pills required per day
- >80% of patients need daily dosage of 1000mg-3000mg
- Patients may pay a higher co-pay (Tier 2) compared to generics for reduced pill burden

Levetiracetam ER market potential

- Levetiracetam market volume in US is growing at an average annual growth rate of 11%
- ~ Out of 600 million units sold per year, 400 million units are consumed for daily dosage of 1000mg - 3000mg
- Product is expected to be commercialized at significant premium to generics

Levetiracetam Daily Dosage



Venlafaxine ER 300mg

- Venlafaxine ER employs SPARC's proprietary Wrap Matrix™ technology
- NDA was filed in US in Q4 FY 2012-13
- Post complete response letter, discussion for additional requirements with FDA completed in Feb 2014
- The FDA requested additional clinical data supporting safety and efficacy of 300mg dose
- SPARC intend to support the FDA requirement with published literature

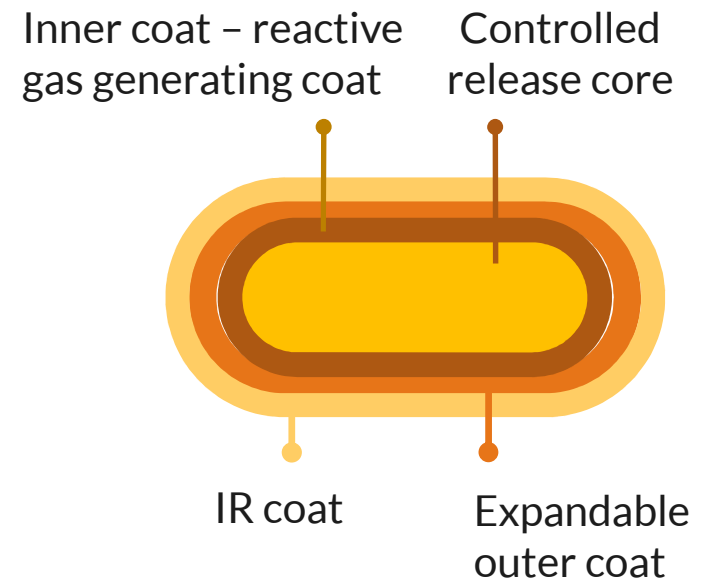


Wrap Matrix™

Baclofen GRS

- Extended release formulation of Baclofen with Proprietary Gastro Retentive Innovative Device (GRID™) technology
- Once daily and recommended fed state dosing for optimal bioavailability and minimal sedation
- Baclofen GRS will be available in 6 strengths i.e., 10 / 20 / 30 / 40 / 50 / 60 mg for individualized dosing and greater dose flexibility
- Offers a steady therapeutically effective level for spasticity
- Patent portfolio comprising of formulation , once a day therapy and indication patents with last patent expiring in 2027

GRID™ Technology



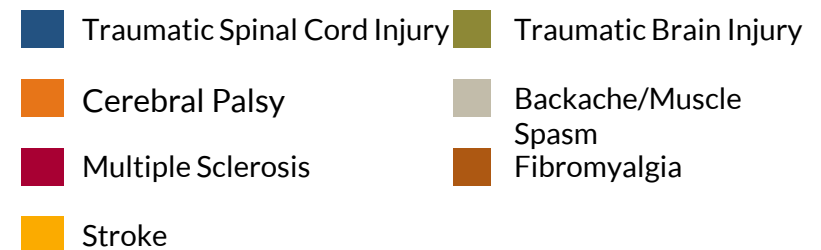
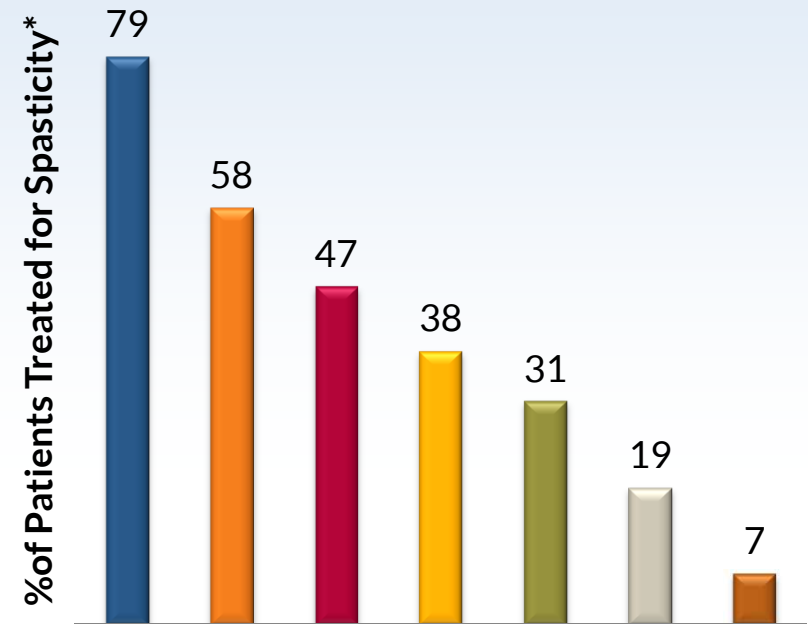
Baclofen GRS - US Commercial opportunity

Market access studies in US

- More than half million people in US suffer from spasticity associated with neurological conditions
- Baclofen is considered as 'Gold Standard' for treatment of spasticity associated with neurological disorders
- KOLs and Payers acknowledged that Baclofen GRS offers sustained efficacy and better patient convenience and compliance
- 5% to 10% switch from Baclofen IR to baclofen GRS is expected

Baclofen GRS market potential

- Baclofen market volume in US (587 million units) is growing at an average annual growth rate of 8%
- Baclofen GRS can be priced at significant premium over generics



Regulatory status update

US -505(b)(2) route

- Phase III, randomized, placebo-controlled efficacy study in 300 patients :
 - 28 sites actively recruiting patients
 - Plan to increase no. of sites to speed up study completion
- Open label safety study is ongoing
- 135 patients PD study to start in Q1 FY 2014-15 to prove once a day dosing

ROW

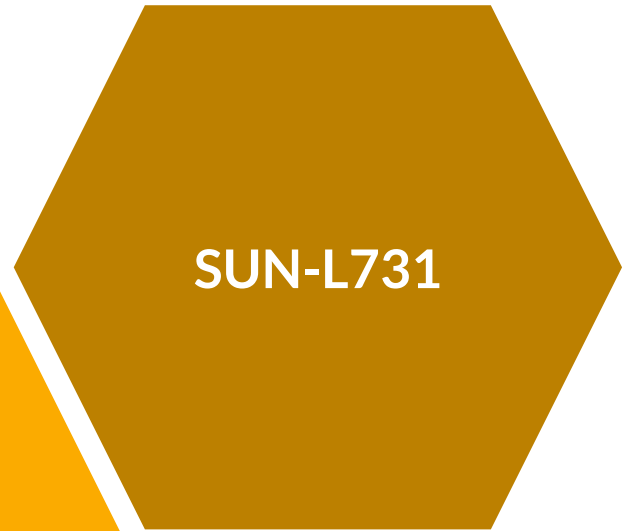
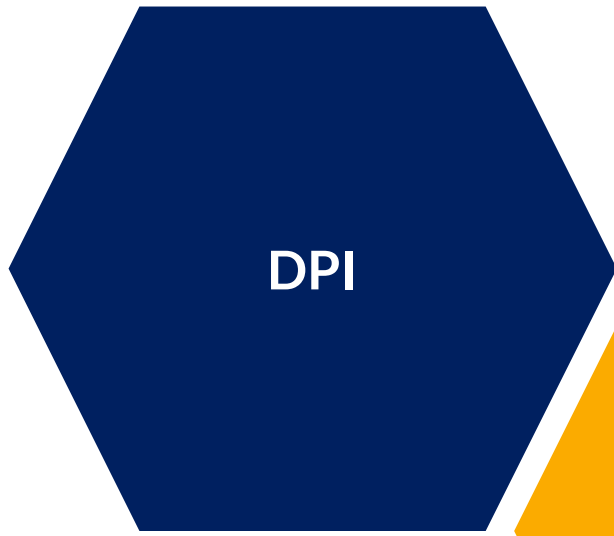
- Planning to file in select EM in FY 2014 - 15

Baclofen GRS for Alcohol Dependence

- 180 patients Phase II clinical study completed in India
- Although Baclofen GRS was found to be numerically better on certain study endpoints, overall statistical significance was not achieved
- Seeking expert opinion on clinical study design for Europe
- We are conducting market access study in Europe and will decide on next steps after its completion



RESPIRATORY



Dry Powder Inhaler

SPARC's DPI is a pre-metered, 60 dose, inhalation activated device for administration of combination of inhaled steroids and bronchodilator drugs

- Uniform dose delivery independent of inspiratory flow rate
- Consistently delivers higher amount of drug to lungs
- Eliminates double dosing and dose wastage
- Provides visual, audible and tactile feedback upon dose administration
- Glow-in-the-dark feature for easy night-time use
- Feature for assisting visually impaired, as reminder to refill device, when 8 doses remain
- Small and convenient for easy to carry
- Compliant to the stringent USFDA and European requirements



Regulatory status update

US

- IND filing in Q3 FY 2014 -15

EU

- CTA submitted to BfARM-Q4 FY 2013-14
- Study to be initiated in Q4 FY 2013-14

ROW

- In one market, CTA submission planned in Q1 FY 2014-15



SUN-597 – Superior pre-clinical profile

- SUN-597 has optimal in vitro potency for glucocorticoid receptors (GR)
- In a high-throughput safety screen, SUN-597 had no significant activity against a battery of 85 receptors, ion channels, enzymes and transporters at clinically relevant concentrations, establishing its specificity for GR
- SUN-597 has in vivo potency and efficacy over a wide range of animal models of allergic inflammation of upper/lower respiratory tract
- SUN-597 is a safe corticosteroid as demonstrated by low systemic side effect potential on single and multiple topical and oral administrations in preclinical models

SUN-597 Nasal – Clinical proof of concept established

Phase I studies of SUN-597 nasal have been completed in India with excellent safety profile

Phase II proof-of- concept study completed in Germany

- At all dose levels SUN-597 demonstrated encouraging efficacy in relieving nasal symptoms
- No significant differences in safety parameters between SUN-597 and placebo.
- Efficacy comparable to literature reported data of Fluticasone and Mometasone

SUN-597 Nasal – Regulatory status update

- Pre-IND meeting with the USFDA with proposed Phase 2 study for identification of optimum dosage and dosing regimen – Completed in Q2 FY 2013-14
- IND accepted by the USFDA
- Phase II study initiated in Q4 FY 2013- 14 and completion expected in Q1 FY 2015-16

SUN -597 - Nasal Commercial opportunity

Allergic rhinitis in US ¹

- Prevalence between 24-28% of total population
 - 2 million missed school days and 100 million missed work days annually
-

US Nasal Corticosteroid Market

- Intranasal corticosteroids are recommended as first-line treatment for moderate/severe or persistent allergic rhinitis
- As per US IMS 2013 data, nasal steroid market is ~ US\$2bn (~55 mn units)

1. As per World Allergy Organization (WAO) data base

SUN-597 Inhalation- Regulatory status update

- CTA approved by UK MHRA- Q3 FY 2013-14
- Phase I/IIa Study initiated in Q4 FY 2013-14
 - Phase Ia-Single dose in healthy for tolerance, safety and PK
 - Phase Ib-Multiple dosing in mild asthmatics to assess safety, PK and pharmacodynamics
 - Phase IIa- Multiple dosing in mild asthmatics to establish Proof-of-Concept
- Completion anticipated by Q2 FY 2015-16

SUN-597 Inhalation - Future development plan

- File IND in the US – Q2 FY 2015-16
- Initiate Phase 2 program in the US –Q2 FY 2015-16

SUN-L731 – A highly selective and potent LTD₄ antagonist

LTD₄ receptor antagonists (CysLT₁ receptor antagonists), are a class of effective anti-allergic therapies for mild asthma and rhinitis

Pre-clinical profile

- Potent and selective LTD₄ antagonist; selective to other isoforms by 1000 fold
- Good oral bioavailability
- Potency ~10 times of Montelukast in LTD₄ induced bronchospasm in guinea pigs
- Efficacy superior to Montelukast in animal model (sensitized BN rat) for eosinophilia
- Fast onset, and long duration of action in LTD₄ induced Lung resistance in guinea pigs; suitable for once-a-day dosing
- High therapeutic index in toxicity studies

SUN-L731 Development status update and plan

- CNS and respiratory safety pharmacology studies for IND completed
- Toxicity studies for IND by Q4 FY 2014-15
- File CTA in the UK by Q1 FY 2015-16



DISCONTINUED PROGRAMS

- Upon commercial assessment and portfolio reorganization, following programs were discontinued
 - SUN 1334 ORAL
 - SUN 1334 OPHTHALMIC DROPS
 - B 09
 - G 44

Robust clinical stage program pipeline

| | |
|--|--|
| Baclofen GRS | Initiated 135 patients PD study to establish once a dosing in parallel to the ongoing Phase III program |
| PICN | Successfully completed EOP2 meeting with USFDA. Clear pathway for registration in metastatic breast cancer obtained from FDA |
| PICN | Established MTD in ongoing Phase I study of PICN in combination with Carboplatin |
| Sun-597 Nasal for Allergic Rhinitis | Filed US IND and Initiated second Phase II study |
| Sun-597 DPI for COPD and Asthma | Initiated Phase I/IIa PK and Proof of concept clinical study in UK |
| Salmeterol and Fluticasone DPI | Initiated Bio Equivalence study in Germany for highest strength of DPI |

Cash flow opportunity – Out-licensing candidates

Latanoprost “BAK free” Ophthalmic Solution

- Peak sales potential in US~ US\$ 25Mn - 50 Mn
- Filed patent application with 2028 expiry

Levetiracetam ER

- Peak sales potential in US ~ US\$30 Mn - 50 Mn
- Product and dose specific granted patents in US -last patent expiry in 2028

Baclofen GRS

- Target NDA filing in 2018
- Peak sales potential in US ~ US\$ 100 Mn
- Product and technology specific granted patents in US - last patent expiry in 2027

Cash flow opportunity – Out-licensing candidates

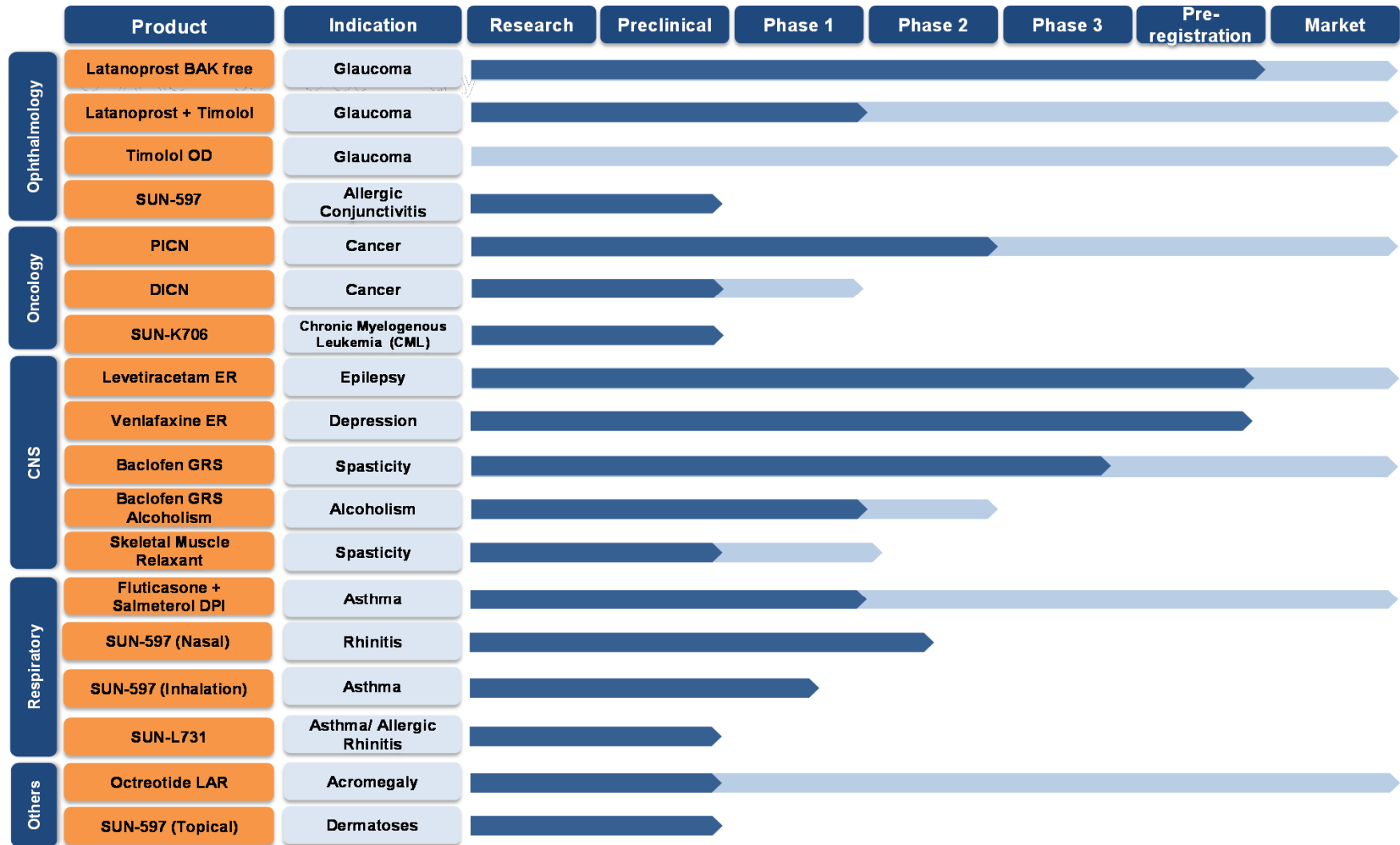
PICN

- Target US filing in 2018
- Peak sales potential ~ US\$ 100 Mn - 250 Mn
- Granted patents in US with 2029 expiry

Potential upsides for SPARC

- Upfront , milestones and royalty income on out-licensing

SPARC Pipeline Summary



■ USA/ EU ■ India



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