

Sun Pharma Advanced Research Company Ltd
17/B, Mahal Industrial Estate,
Mahakali Caves Road,
Andheri (East), Mumbai 400 093 India
Tel.: (91-22) 6645 5645
Fax.: (91-22) 6645 5685
CIN: L73100GJ2006PLC047837
www.sunpharma.in



SPEECH DELIVERED BY MR. DILIP SHANGHVI, CHAIRMAN AND MANAGING DIRECTOR OF SUN PHARMA ADVANCED RESEARCH COMPANY LIMITED AT THE 9TH AGM OF THE COMPANY

Dear Fellow Shareholders

On behalf of the Board of Directors I take pleasure in welcoming all of you to the 9th AGM of your Company.

2013-14 was a remarkable year not only for the technologies and products at SPARC, but also in terms of making SPARC future-ready, preparing the company for future growth with several organizational changes. We brought in new leadership with SPARC's new CEO, Anil Raghavan. Anil brings rich skills in managing of biotech and drug discovery R&D processes with extensive experience in India and abroad. Anil will bring in important direction to the team at SPARC as we gradually move closer from lab to market.

2013 was an important year in SPARC's journey of discovery. Important delivery-system based products like Latanoprost and Timolol eyedrops and the important anticancer PICN received regulatory approval and reached their first market, India. Several important technologies and molecules also progressed to their next stage of development. Decisions were made about important clinical milestones and the countries of choice for subsequent clinical work for several projects. I shall share some of these developments with you today.

During the year, SPARC earned royalty income from a subsidiary of Sun Pharma, related to the sales of Liposomal Doxorubicin injection in the US. SPARC also earned a milestone for the registration of PICN, a novel anticancer, in India. While this is a good beginning, we are quite optimistic about future opportunities to monetize SPARC's products and technologies across markets.

Currently, products based on six NDDS platform technologies are being developed, across oral, injectable, inhalation and topical dosage forms.

SPARC also achieved important progress in the development of several New Chemical Entity (NCE) projects. The team is currently working on three important new molecules.

Performance

The financials for 2013-14 have been published and are available with you. This year your company showed its first ever profit of Rs. 30 crores and EPS of Rs. 1.28 as against net loss of Rs.22.5 crores last year. The total income for FY13-14 at Rs. 177 crores was significantly higher than the Rs. 88.8 crores recorded last year. This improvement was driven by technology related income, mainly for Liposomal Doxorubicin, and a few other products. Just as a reminder, milestone incomes are non-recurring in nature, while royalty payments continue for the time the product is in the market.

At SPARC our focus has been developing innovative drug delivery technologies and new molecules. For our products, we own the intellectual property and register our innovations across world markets. Like

Sun Pharma Advanced Research Company Ltd
17/B, Mahal Industrial Estate,
Mahakali Caves Road,
Andheri (East), Mumbai 400 093 India
Tel.: (91-22) 6645 5645
Fax.: (91-22) 6645 5685
CIN: L73100GJ2006PLC047837
www.sunpharma.in



any research company, we earn when and if these technologies are licensed out or brought to market by our partners.

Drug discovery is a high return business, but with a different risk profile than the generic business. Innovation needs large investments over fairly long timeframes; it requires a company to apply fresh thinking to scientific problems. The outcome is uncertain, some projects may have to be dropped if results do not meet our expectations, or a competitive molecule is quicker to market, or if a generic alternative enters the market. But even if one project out of many makes it to market, the returns can be of a different magnitude than for the generic business.

Even as we discuss some exciting projects today, I want you to bear this inherent uncertainty in mind. In the longer term, I am fairly confident that we will create intellectual property and build value from the research we do at SPARC.

Now I'll discuss the projects and significant events related to them. I'll address these therapy-area wise.

First area that I'll talk about is Oncology. This continues to be an area attracting researchers the world over with exciting new approaches, and SPARC is no exception. I'd like to talk about two approaches, one of which is delivery system based using our proprietary nanotecton technology, and the other is new molecule based, a tyrosine kinase inhibitor also called a T1K1 inhibitor which we're developing for CML, or blood cancer.

I'm immensely proud to share with you that PICN, our nanotecton based anticancer, has been registered in India, its first market. Paclitaxel Injection Concentrate Nanodispersion is a patient and doctor friendly formulation of the anticancer, Paclitaxel. The largest use for Paclitaxel is in the treatment of early as well as metastatic breast cancer. Since this formulation delivers the drug directly to the tumor site, it is free of side effects on other important organs such as the heart and kidney. PICN does not require any pre-administration unlike other drugs, so no pretreatment with anti-allergy drugs or steroids is required. PICN will now be tested in the US in Phase III for metastatic breast cancer. Phase II trials in several other cancer indications will also begin in the US. I look forward to sharing more positive news about our flagship product, PICN in the years ahead.

The second oncology drug I am going to talk about is SUN- K706. Sun- K706 belongs to a class called tyrosine kinase inhibitors or TKI. Sun-K706 is being developed for the treatment of a resistant, difficult to treat form of Chronic Myelogenous leukemia (CML), or what we call blood cancer. Not only does this treat a resistant form of the disease, but it may possibly have lesser side effects than newly introduced drugs like Ponatinib. Sun- K706 is currently in preclinical testing, and I'm rather excited by the data we've gathered so far. I expect to have more information to share about Sun- K706 as we move to the next stage of IND filing.

With products in the market as well as several projects in development, Ophthalmology leads amongst our focus areas. This year we have interesting achievements to share. Most of you must be familiar with Glaucoma, a condition where extensive pressure builds up inside the eye. This condition can even lead to loss of vision if not treated in time. Doctors prescribe drugs like Timolol and Latanoprost to lower the eye

Sun Pharma Advanced Research Company Ltd
17/B, Mahal Industrial Estate,
Mahakali Caves Road,
Andheri (East), Mumbai 400 093 India
Tel.: (91-22) 6645 5645
Fax.: (91-22) 6645 5685
CIN: L73100GJ2006PLC047837
www.sunpharma.in



pressure. However most eyedrops use preservatives like BAK that may cause additional damage to the eye surface.

We addressed this issue by developing a preservative-free form of Latanoprost, one of the most commonly prescribed drugs for glaucoma. In Latanoprost BAK-free, the drug is solubilized without using surfactants and preservatives, using SPARC's proprietary SMM technology. After an extensive Phase III program, the NDA for BAK-free Latanoprost was filed in the US, as well as in four emerging markets. We expect to file Latanoprost BAK-free in several more emerging markets going ahead, and are evaluating alternatives for commercialization.

The second problem that we chose to address was about the number of times glaucoma drops have to be instilled. Most patients are asked to use their glaucoma drops several times a day, and compliance is an issue. SPARC then developed Timolol eyedrops with GFR technology, so that eyedrops need to be instilled only once a day.

The next logical step was to combine both these technologies, GFR and SMM. Combination Latanoprost and Timolol drops would address both the issues, eye surface damage and irritation. SPARC developed Latanoprost plus Timolol eyedrops, and this was successfully brought to market in India. This combination product, allows the convenience of once-a-day drops, and offers the same efficacy as innovator drugs, Xalatan® once daily and Timoptic® twice daily when used together. We have obtained advice from regulatory consultants for potential EU filing and are presently evaluating the commercial potential. After reassessment, we are also planning to revisit USFDA specific guidance. These eyedrops will be filed in select emerging markets this year. I am quite excited about this opportunity.

I will now talk about the CNS programs we're doing at SPARC and this benefits from our extensive therapy area experience. In CNS too, technology has been demonstrated, and products have been brought to market using work done in our labs.

The first technology which I'm going to talk about is Wrap Matrix. In Wrap Matrix, a highly soluble product that needs to be taken several times a day is modified into a compact, once-a-day product. Several products have been brought to market in India, and several more ANDAs filed. Today I will talk about two important projects, Levetiracetam, an antiepileptic and Venlafaxine ER 300, an antidepressant.

SPARC has done extensive work with Levetiracetam, which currently is taken several times a day. SPARC has developed wrap matrix based tablets of 1000 mg and 1500 mg of Levetiracetam, which may need to be taken once or twice a day, in addition to better control over epileptic seizures. An NDA had been filed with the USFDA, and a complete response letter was subsequently received. We will now be

Sun Pharma Advanced Research Company Ltd
17/B, Mahal Industrial Estate,
Mahakali Caves Road,
Andheri (East), Mumbai 400 093 India
Tel.: (91-22) 6645 5645
Fax.: (91-22) 6645 5685
CIN: L73100GJ2006PLC047837
www.sunpharma.in



conducting an additional pharmacokinetic study as required to complete this submission. We expect to complete the study and file the data by Q2 FY15.

Venlafaxine ER 300 mg, an antidepressant, is the second product, I'd like to highlight. We have filed an NDA for this product in Q4 FY13, and subsequently received a complete response letter. USFDA wanted data to support safety and efficacy of a 300 mg dose. Subsequently, SPARC met with FDA officials and offered to provide supporting data from published literature to support the higher dose.

Now I'll move on to the next technology, GRID. As I've have shared previously, Gastro Retentive Innovative Device or GRID is a once-a-day system to administer drugs that are absorbed only in stomach or the small intestine.

Baclofen GRS, a once-a-day capsule to treat muscle spasticity, based on GRID, has now been selling in India for over four years now. Ideally, we'd want to take Baclofen GRS to international markets, beginning with the US. Baclofen GRS is currently in Phase-III efficacy study in 300 patients over 30 sites in the US. A safety study in 200 patients is also underway. A study to show the efficacy of Baclofen GRS in a once-a-day formulation will start in Q1 FY15.

After oncology, ophthalmology and CNS, the next therapy area I would like to talk about, is Respiratory. I have previously spoken to you about SPARC's DPI, which is a pre-metered, 60 dose, inhalation activated device for administration of combination of inhaled steroids and bronchodilator drugs. Salmeterol and Fluticasone DPI has already been approved and launched in India, and we are doing the groundwork for taking this DPI to international markets. For the US market we are planning to file an IND for this product in Q3FY15. For Europe, we have submitted the clinical trial application (CTA) for the first study in the clinical program to the German regulatory authority, as well as the Ethics Committee. The CTA has been approved and the study has been initiated in April 2014. For emerging markets, we have identified one market where we plan to submit our filing in Q1FY15. For this project, to sum up international development continues phase-wise even as we continue gathering rich experience with users in India.

The second respiratory product I'd like to highlight is SUN-597, a soft steroid being developed for allergic rhinitis, asthma and other inflammatory applications. Current products being developed for this molecule are SUN-597 Nasal Spray for allergic rhinitis, as well as an Inhaler for Asthma and COPD. In preclinical testing, SUN-597 had offered a good preclinical profile with good safety, which I had shared earlier. It had also shown *in vivo* potency and efficacy over a wide range of animal models of allergic inflammation of upper/lower respiratory tract.

For SUN-597 nasal spray, we have completed Phase-I clinical program in India, and it was found safe and well tolerated. Last year we conducted a proof-of-concept Phase-II study in Germany, where we found that all three doses tested were superior to placebo for efficacy, the safety profile being very similar to placebo. The efficacy was comparable to literature reported data of marketed products like Mometasone and Fluticasone propionate. We submitted an IND which was accepted by USFDA, and we have initiated a Phase-II study in this quarter with completion likely by Q1FY16. So, considering the

Sun Pharma Advanced Research Company Ltd
17/B, Mahal Industrial Estate,
Mahakali Caves Road,
Andheri (East), Mumbai 400 093 India
Tel.: (91-22) 6645 5645
Fax.: (91-22) 6645 5685
CIN: L73100GJ2006PLC047837
www.sunpharma.in



safety profile for SUN-597 Nasal Spray, and with about similar efficacy compared to marketed products, we believe we have a strong product under development.

The next product we're developing with SUN-597 is a metered dose Inhaler for COPD and Asthma.

We submitted a clinical trial application for this product with UK MHRA, which was subsequently approved and the study has been initiated. This study consists of three parts; Part-I is a single dose study in healthy volunteers, Part-II is multiple doses in mild asthmatic patients, and Part-III is a proof-of-concept study for SUN- 597 DPI.

The study is expected to be completed by Q2FY16, after which we plan to file an IND in the US and conduct a Phase-II program.

SUN-L731, a selective and potent LTD₄ antagonist, is also being developed for mild to moderate asthma. The preclinical profile of SUN-L731 shows that it is potent and selective, with good oral bioavailability. It is almost 10-times more potent, more effective and longer lasting compared to Montelukast, with a faster onset of action. There are no safety issues for SUN-L731, and it has a high therapeutic index. Safety pharmacology studies as well as toxicology studies are underway for SUN-L731, and we plan to file a clinical trial application in the UK in Q1FY16.

Outlook

Since SPARC is largely doing innovative work, it is imperative for SPARC to strike a reasonable balance between risks and rewards with the projects that it pursues. Over the past few years, SPARC has attempted to strike a balance between medium-term and long-term R&D projects.

Broadly, our New Drug Delivery System (NDDS) projects are likely to reach at market in the medium-term whereas our New Chemical Entity (NCE) projects may take longer to reach market.

While we're satisfied with the progress on our projects so far, we recognize that we have quite some distance to go before we reach market. The basic premise and potential that we sought to address when we started the company, remain unchanged.

Team SPARC

Research calls for technical skills of a high caliber, domain expertise that is equivalent to the best available internationally, and people who are inspired and enthusiastic about the work they do.

We believe in our team, will continue to invest in it, and in building the right environment for innovation.

Thank you.

Place: Vadodara
Date : July 31, 2014

Dilip S. Shanghvi
Chairman & Managing Director