Taking flight
Taking flight
A female bias for the blues?

For long, scientists have observed that women are more vulnerable to depression. For long, this has been attributed to turns to an excitable nervous system, the opposing tugs of work and family. Researchers are now looking for a scientific reason for this discrepancy and it may be because of genes. Scientists say that depression in women is a global phenomenon cutting across class divides, spanning life experiences. Several genes, along with the surges in hormones may influence brain chemistry and trigger depression. A risk factor linked to ruminating, over thinking, mulling over issues and re-living sad incidents is more common in women and could lead on to depression. However, half the risk could be genetic, with areas that cause this deep sadness now identified. And these genes act in concert with estrogen receptors with variations in sex hormones in a complex interplay of hormones, neurotransmitters and receptor activation.

As responsible as genes and neurotransmitters is the womanly inclination to brood over experiences, mulling them over and over without reaching a solution or simply moving on. Research shows that women who habitually ruminate but are not depressed are prone to develop depression later. Thinking overmuch can be vulnerability too.

We launched this year a form of the long acting antiepileptic Drorita EIR. Internationally this medication has been approved for migraine prophylaxis. It has also found use as an antimuscarinic and a long term mood stabilizer in patients with bipolar mood disorder, that are resistant to or unresponsive to lithium with lesser side effects, thus increasing compliance to treatment. Olanzapine injection was launched for the first time in the country and very quickly after international launch. This medication helps control aggressive agitation associated with schizophrenia and bipolar mania.

Arpizol, our brand of one of the latest antipsychotics introduced, was brought to the Indian market based on our own bulk. The medication in Arpizol treats a wide range of symptoms of schizophrenia both the positive and negative symptoms. A common problem with long term use of antipsychotics is the emergence of tremors and a Parkinson-like shuffle, stiffness called EPS or Extrapyramidal Syndrome; because of the way this drug acts it has a lower likelihood of EPS than older medications like haloperidol. A lesser likelihood of relapse; significantly better response on learning, and non-zombie responses are other pluses. Some of these features may make this the drug of choice. Lesser weight gain, lesser likelihood of diabetes or elevated cholesterol that otherwise interferes with therapy, are other features in Arpizol’s favour. Delusions, disordered thinking, hallucinations characterize schizophrenia. In schizophrenia, by the end of 2 years, 75% of the patients are not taking medication. Doctors say relapses take something back from the patients, making it harder to get back to normal. Injections and long acting medications offer advantages of smoother dosing without treatment interfering peaks and troughs.

Drugs like Aripiprazole, the medication in our brand Arpizol, appear to be better at preventing emotional blunting, withdrawal and depression and help with alertness and memory. Nexito is our brand of escitalopram that had been introduced last year as an antidepressant. The USFDA recently approved this medication for the treatment of generalized anxiety disorder a disorder that affects close to 3% of the US population; also a vast majority of the patients with depression. These medications have been introduced this year as an antidepressant. The USFDA recently approved this medication for the treatment of generalized anxiety disorder a disorder that affects close to 3% of the US population; also a vast majority of the patients with depression. 

Seek in the stillness of nature

The cover shows 2 images from breakthroughs in neuroscience: a neuron, an MRI scan. Two ideas that took learning from one field and in an inspired moment, “a flash of lightning” showed how best they could be applied to another field, another application.

How did this happen?

Perhaps it took depth of understanding, an appreciation of fine details and meaning. But from here to be able to think beyond, this jump in imagination, this spark and the will to see it through, perhaps it takes a magical “something more.”

1887. Dr Cajal’s work on the basic structure of the nervous system, the neuron. Work that happened almost a hundred years ago, but has since remained unchanged. Work that upset long cherished beliefs in neuroscience. And established that the nervous system is made up of discrete neurons.

An excited Dr Cajal wrote, “a flash of lightning, the nerves brownish black, their finest branches on a transparent yellow backdrop, sharp as a sketch with Chinese ink... new facts, ideas posted in my mind... a fever for publication devoured me.”

As visionary was Dr Lauterbur’s work on the medical application of MRI. This work that earned him and Sir Peter Mansfield the Nobel in 2003. Yet the basic science that the MRI builds on, was known since 1946. It took till 1973 and the genius of one man for this brilliant application to be thought through. Dr Lauterbur took a chemist’s technique to study solutions with magnetic fields and perfected it into a way to visualize the body. He grasped that in their study of solutions, chemists were missing out an important data; data, that could be used to put together 3 dimensional molecules.

Today, precise MRI generated images of the joints, bones and the brain make a detailed study almost routine. So that a quick and accurate diagnosis can be made.

As we move ahead to drug discovery, it is to insights such as these that we turn. In the pursuit of a special “something more.” Our very own “flash of lightning.”

And the insistence to see an idea through.
Mirroring optimism and a strong trend in the economy, the domestic pharma market at the end of the year to March 04 showed a growth rate in excess of 7.3%. Specialty therapy areas grew much faster, 12%, with select areas like diabetes: 24%, and cardiology: 18% growing much faster. Formulations accounted for most of our sales—domestic formulations were 60% of sales, export formulations were 6.8% of sales.

Like every year, work done at our research center, the Sun Pharma Advanced Research Center (or SPARC), helped to bring important products to market; some of these used technology modifications for a product that’s easier to take.

Our experience in designing and making these products for India will later help us register these products for developing markets, and eventually take these to challenging regulated markets.

At our research labs, processes for 16 bulk actives (the medically active ingredient in a tablet or capsule which is responsible for its action) were developed. For some of these bulk actives we would be among a handful in the world. Some of these bulk actives enabled us to make formulations available in the Indian market at a sensible price.

The work that we have done so far in setting up marketing teams in select international markets is working well. The presence that we have created with an expert team, systematic call coverage, and brand building is beginning to earn us prescriptions and recognition as a high quality company. In most of these markets since we are a relatively small player, the opportunity ahead is tremendous; we are putting the right plans in place to grow at 40-50% for the second year in succession. This in other words means we are doubling our international formulations business every two years. Our approach of applying the same template that has worked for us in India is on the right track.

Increasing economic and political uncertainty coupled with peer group pressure and the pressures of modern living have caused this sector to grow at a good rate. Yet global research indicates that mental illness is largely undertreated both in the developed and developing world; in more than half the countries surveyed affecting over 10% (see box).

The segments that Synergy participates in continued to be competitive. As we’d shared earlier, this competition has intensified from companies that used to compete in the large volume therapy areas earlier as in antibiotics, tonics and vitamins. These were companies focused for the long term with a good grasp of marketing. These companies continued to be among the first to bring new products to market. It is to the divisions credit that several of the recently launched products like Arpizol, Nexito (both at number 1 rank) are products of choice for their molecule, with market shares in excess of 35%.

Another interesting development, which is perhaps, a harbinger of events for the long term is the renewed interest from multinationals in these therapy areas and a keenness to introduce and invest in the latest brands that they have launched internationally. Although these products are priced at a premium there seems to be a greater willingness for co-marketing deals and serious brand building even on behalf of companies that for years had no more than a marginal presence.

It is to the field force’s credit and standing with speciality customer groups that it continues to add prescription share and reach top ranking with new products.

Among Synergy’s key therapy areas: Antiepileptics, antidepressants, antipsychotics continued to predominate. New products were introduced in the antipsychotic and antiepilepsy segments. Across these segments products approved first for one indication continued to find use in the treatment of another. Antiepileptics are routinely prescribed in non-neurological ailments and psychiatric disorders ranging from trigeminal neuralgia (pain along the length of the trigeminal nerve), neuropathic pain, migraine, essetial tremor.

We continue to be the fastest growing company among the top 5 companies in the country.

Increasingly, Indians are seeking medication for mental health. A survey of 60,643 patients carried out in 14 countries:

"In some countries there just is not this tradition of public opinion and speaking your mind" said a Harvard Med School researcher leading the study.

"In every country there is a hidden or unhidden stigma" said an expert from WHO. "People are reluctant to admit they have mental problems."

"In the developed countries, 36-50% of the people with serious symptoms were untreated; in developing nations 76-85% of the cases were untreated."

"In most countries 9-17% of those interviewed had some episode of mental illness in a year."

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(Mental Health: for most, still a grey area

Some facts from a survey of 60,643 patients carried out in 14 countries

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(associated Press Report/June 1, 2004)
In new molecule research, good progress was made in three therapy areas of our interest, and one lead, the company’s first molecule, entered phase one clinical trials in Europe. A number of interesting leads were identified for preclinical work and development.

In novel drug delivery systems, good progress was made in the 4 therapy platforms identified—oral CR/SR, biodegradable membranes, DPI, targeted drug delivery. Two delivery systems are slated to enter clinical trials by year end.

Caraco’s turnover for the year ending December 2003 crossed $45 mill, up 103% from $22.4 mill in the previous year. Caraco benefited from synergies of bulk active manufacture sourced from our approved sites, resulting in lower raw material costs and better margins; with the bulk actives for four of Caraco’s key products being sourced from our plants.

At Caraco, sales this year were driven by increasing sales of metformin and metoprolol, and with the bulk actives for four of Caraco’s key products being sourced from our plants.

Brands in our core therapy areas account for a large part of our business in India. Over 72% of domestic formulation sales is from psychiatry, neurology, cardiology, diabetology, gastroenterology. Our top 15 brands accounted for about 32% of domestic formulation sales, which means we are not greatly dependent on any single product or product range. 150 brands featured among the leading brands for that molecule. This year, 48 new products (not counting line extensions) were launched to bring the latest treatments to market. We added to our field force, and created 3 more divisions at year end. We now have 15 divisions, and with strong operational controls and systems, have built a team that is amongst the best in the country.

This year was good on the international front too. We increased our stake in our US subsidiary Caraco to over 63% by buying out stock from 3 large shareholders. Caraco is well set for a good future, with sales of over $45 mill for 2003, 14 ANDAS received and marketed, a decent pipeline of filings, and interesting products being readied for filing. Caraco has shared a forecast of 20-25% growth for 2004. A separate section talks about Caraco at length.

Retail store data is one measure of performance. Another important measure is how customers rate the company, and the market research tool that offers this data is the CMARC audit. The CMARC audit tracks actual live prescriptions for insight into how our customers view us and how they prescribe products in real time. Our prescription share for the March–June 2004 period is 2.09%, up from 2.03% last year.

We’ve identified and built on two ways of adding market share. One of these, is specialist task force teams that focus on one disease or therapy. The other is the creation of parallel divisions. On both these fronts, we’ve taken a few important steps.

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First, a brief look at how we have done financially.

- Considering Sun Pharma standalone (without counting the turnover of the subsidiaries) for 2003-2004, turnover was Rs. 9597.5 mill.
- Domestic formulation was Rs. 5603 mill.
- International formulations or the brands that we sell outside India was Rs. 609 mill, the second year of robust growth.
- International bulk was Rs. 1533 mill. Most sales were to regulated markets.

**TWO ACHIEVEMENTS**

Our bulk active plant at Panoli received USFDA and Australian TGA approval this year. Our tabletting facility at Halol received USFDA approval. This takes the total number of USFDA approved sites to 3.

We’d begun to build a worldclass manufacturing facility at Jammu last year, and this is now operational. With manufacturing capacity for 1000 mill tabs/ year, this 90,000 sq ft international class plant is being used to address increasing domestic demand. From start to finish, this plant was put up in less than 14 months.

We also applied these manufacturing and project scale up skills to new markets. Our Bangladesh plant, our first joint venture overseas, is now close to beginning commercial production. In the last 3 years, with these new sites at Dadra and Jammu, and additional manufacturing capacity at Panoli and Halol, takes the total manufacturing capacity to 528 KL of bulk actives and 6000 mill tabs/year.

Speciality bulk actives at Rs 2683 mill accounted for 30% of sales. 60% of this was to the international regulated market for bulk actives and 6000 mill tabs/ year.

Research and Development

R&D expense increased from Rs. 657 mill to Rs. 1077 mill, up 64%. Cumulatively, our spend is now is excess of Rs. 2934 mill. Of the spend this year, revenue R&D increased 63% from Rs. 294 mill to Rs. 479 mill. Total R&D expense was 12.83% of sales, (9.14% last year).

We commissioned a new R&D site in Baroda, and a new product development center in Mumbai. Our new site in Baroda, SPARC Tandalja, is spread over 200,000 sq ft across 16 acres and offers a world class environment for R&D. This team works on innovation based projects, both in new chemical entity (NCE or new molecule) and novel drug delivery systems (NDDS or a way of using technology to deliver an older medicine in a manner that is more convenient or patient friendly).

The US market is very important in our long-term plans. We shifted our Mumbai R&D is now is excess of Rs. 2934 mill. Of the spend this year, revenue R&D increased 63% from Rs. 294 mill to Rs. 479 mill. Total R&D expense was 12.83% of sales, (9.14% last year).

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The US market is very important in our long-term plans. We shifted our Mumbai R&D product development center from a 6000 sq ft lab to new premises with over 50,000 sq ft We’ll be increasing the number of scientists to 125 over the next year. This lab is dedicated to new projects, both in new chemical entity (NCE or new molecule) and novel drug delivery systems (NDDS or a way of using technology to deliver an older medicine in a manner that is more convenient or patient friendly).

With this framework in place, we expect a robust rate of growth to be maintained over the next two years and beyond.
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Speciality bulk actives at Rs 2683 mill accounted for 30% of sales. 60% of this was to the international markets.

Domestic formulation was Rs 5603 mill.

Domestic product sales were Rs 3341 mill, growing 11% over the second year of robust growth.

Total turnover was Rs 9597.5 mill, the second year of robust growth.

Our dosage form exports now reach 26 markets. Approvals were recently received from two important markets- Brazil and Mexico. Product registrations in the Bangladesh joint venture have also been received, these new international markets will add to our growth.

In existing markets, our brand building effort, with well planned marketing strategy, 249-person strong field force, regular doctor coverage, promotional cycles and marketing inputs is beginning to fetch results.

We've taken our experience with technically complex products one step ahead. In the Indian market, we've launched several products like Lupride Depot, a depot dosage form that is prescribed in prostate cancer/endoemetrosis. The technology used in this product is such that the drug releases gradually over a month. We have now begun the process of registering these products in key markets like China. We are also participating more actively in these markets with participation in events, conferences, doctor group meetings, CMEs, exhibitions, in order to build company image.

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The US market is very important in our long-term plans. We shifted our R&D product development center from a 6000 sq ft lab to new premises with over 50,000 sq ft We'll be increasing the number of scientists to 125 over the next year. This lab is dedicated to the US market.

Across projects- both innovation and reverse engineering, our tally of patent filled stands at 321, with 33 patents received. In all, 48 new products (not including line extensions) were launched in the domestic market. 21 used a different delivery system or technology. 5 ANDA submissions were made from an Indian site, in addition to the 7 filings Caraco will make in 2004.
Innovation based projects

In novel drug delivery systems, good progress was made in the 4 therapy platforms identified--oral CR/SR, biodegradable membranes, DPI, targeted drug delivery. Two delivery systems are slated to enter clinical trials by year end.

Key international markets

Caraco's turnover for the year ending December 2003 crossed $45 mill, up 103% from $22.4 mill in the previous year. Caraco benefited from synergies of bulk active manufacture sourced from our approved sites, resulting in lower raw material costs and better margins; with the bulk actives for four of Caraco's key products being sourced from our plants.

At Caraco, sales this year were driven by increasing sales of metformin and metoprolol, and in both these it has become an important player. Also, smaller speciality products for which approvals were received last year showed increasing sales. In 2003, Caraco invested $2.5 mill in plant expansion and upgradation.
Key Highlights

- Net profit Rs 25944* mill on a turnover of Rs 9598 mill
- Market share at 3.11% in March 2004 up from 2.99% in March 2003
- Growth rate is the highest of the top 5 pharma companies
- Number 1 rank in cardiology, a breakthrough. Continue to be number 1 with psychiatrists, neurologists. Among the top 4 with 8 customer classes.
- One molecule enters clinical trials in Europe.
- International dosage form sales at Rs 609 mill.
- Products launched in the last 3 years account for 28% of domestic formulation sales.
- USFDA approval for the Panoli bulk active and Halol formulation sites; now a total of 3 USFDA approved sites.
- Halol site also receives UKMHA approval.
- Two R&D sites with 250,000 sq ft space commissioned: SPARC Tandalja, Baroda, SPARC Mahakali, Mumbai.
- New formulation units* at Jammu and Dadra now operational, massive expansion at the Panoli bulk active site.
- Caraco posts a turnover in excess of $45 mill for December 2003, projects a 20-25% growth, to file 7 ANDAs in 2004.
- Sun Pharma commences ANDA filings from an Indian site: 5 ANDAs filed till March 2004.

*MILMET

Glaucoma is an eye disease in which the normal fluid pressure inside the eyes slowly rises, leading to vision loss—or even blindness. Open-angle glaucoma is the most common form of the disease. At the front of the eye, there is a small space called the anterior chamber. Clear fluid flows in and out of the chamber to bathe and nourish nearby tissues. In glaucoma, for still unknown reasons, the fluid drains too slowly out of the eye. As the fluid builds up, the pressure inside the eye rises. Unless this pressure is controlled, it may cause damage to the optic nerve and other parts of the eye and loss of vision.

Milmet continued to build market share with ophthalmologists with high service and new products. Milmet’s products now span the entire ophthalmic basket, with products for the treatment of glaucoma, dry eye, allergy infections, as also viscoelastics, ophthalmic nutraceuticals, cycloplegics, and anesthetics.

Antiglaucoma and dry eye management, are very large and high growth chronic segments and an important part of Milmets’ business.

In view of the tremendous potential in ophthalmology a new division called Avesta was launched early in April this year. Glaucoma treatment is the division’s forte, with the brand Timolet amongst the largest brands in this area, and the introduction last year of Latoprost, one of the latest advances in glaucoma care. Timolol GFS, a once a day drug delivery system offers convenience and compliance advantage which is an important plus for eye drops that require repeat instillation. On long term use, it was seen that preservatives that are used in eyedrops often cause irritation. This was the rationale behind the launch of Brimosun P, a preservative free antiglaucoma product.

Patient awareness camps and the distribution of patient information on glaucoma earned Milmet goodwill in the market.

Dry eyes are a frequent complaint with most of us. While earlier it was believed that the causes were related to a reduction in the tear layer in the eyes, it is now believed that the real culprits are eye strain due to computer overuse, hours of television watching and extended hours spent in an air conditioned environment. Preservative free Eyemist is an important product launched for the treatment of dry eyes. Duodrop and Cyclomune are two more products making up the range. Cyclomune, a product introduced for the first time in India, is a specific treatment for serious dry eyes which can be quite threatening, and it treats this ailment at its root. Cyclomune has been termed a new advance in dry eye treatment. I-site, a specially formulated antioxidant combination for use in age related degenerative eye disease, is quickly emerging as one of Milmets’ key brands. With its comprehensive combination of nutrients like L-glutathione, Lutein, Vit C and E, betacarotene, I-sites offers comprehensive support in treatment of diabetic retinopathy and age related macular disorder.

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**FINANCIAL RESULTS**

<table>
<thead>
<tr>
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<th>Year ended 31st March, 2004 (Rs. Millions)</th>
<th>Year ended 31st March, 2003 (Rs. Millions)</th>
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<tr>
<td>Total Income</td>
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<td>Profit after tax</td>
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<td>Transfer to various Reserves</td>
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<td>Rate of dividend on equity shares</td>
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<td>100%</td>
</tr>
<tr>
<td>Book value per equity share (Rs. 5 paid up)</td>
<td>93</td>
<td>75</td>
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(* before prior period adjustment, * shown at Pre Bonus rate for the purpose of comparison. The Post-Bonus Dividend rate is 65%.)

**Dividend**

An interim preference dividend of 6% p.a. (previous year 6% p.a.) on paid up amount of preference shares and an interim equity dividend at the rate of 65% post bonus (equivalent to 130% pre bonus-previous year 100% p.a.) for the year ended 31st March, 2004 was paid to the shareholders of the Company whose names stood on the register of the members on 13th December, 2004. Your Directors recommend that the interim dividend on preference and equity shares be treated as final.

In order to make an impact with the respiratory segment, especially the treatment of asthma, the Radiant division was launched last year. The division has earned a very good franchise with chest physicians in this short period, and is already ranked 4th.

The division worked to expand the respiratory market, especially Asthma, by patient awareness and training for the medical profession to identify and treat respiratory disorders accurately. The field force regularly conducts free asthma and allergy check-up camps, conducts seminars and video shows that educates about asthma related queries.

Radiant was amongst the first to start a series of CME workshops for post graduate medical students in respiratory disease where eminent speakers educate and share their experience on asthma-related topics. Workshop related to spirometry, lung function tests, device demonstration are also undertaken during the workshop.

Tiotrop, one of the latest drugs for COPD (Chronic Obstructive Pulmonary Disorder) was launched by Radiant and almost 1000 new patients per month are taking this drug.

Nezaflo, fluticasone nasal spray, has been well accepted by the chest segment. In a short 10 month span it has topped the number of prescriptions among fluticasone nasal spray brands, some of which have been marketed for over 3 yrs.

**Stress can choke asthmatics**

People with near fatal asthma attacks are more likely to have food allergies and report feeling stressed before the attack. People with near fatal attacks were more likely to report stress as an asthma trigger as well as high exposure to cigarette smoke and pets.

“those in the near fatal attack group were more apt to have reported a food allergy or have been to a restaurant or party.”

(The Economic Times, Reuters story, June 16, 2003)
Annual General Meeting and its adjournment

As the Shareholders are aware, the Audited Profit and Loss Account for the year ended 31st March, 2004 and the Balance Sheet as at the said date could not be laid before the Shareholders at the Annual General Meeting (AGM) of the Company held on 30th December, 2004 as the impact of the Scheme of Amalgamation/Merger of Philox Pharmaceuticals Ltd. with the Company w.e.f. 1st March, 2004 could not have been incorporated in the accounts of the Company for the financial year 2003-2004, until the Scheme of Amalgamation/Merger was sanctioned by the Board for Industrial & Financial Reconstruction (BIFR). Accordingly, the said AGM was adjourned sine die for consideration of the audited accounts, the report of the Directors and the Auditors thereon for the year ended 31st March, 2004 and confirmation of payment of interim dividend until after the sanction of the Scheme by the BIFR. Meanwhile due to likely delay in the approval by BIFR, the Company approached the Honorable High Court of Gujarat for Amalgamation/Merger of Philox Pharmaceuticals Ltd. with the Company under section 391 to 394 of the Companies Act, 1956 and obtained the approval of the shareholders to the same at their meetings held on 6th April, 2005. The Scheme of Amalgamation/Merger of Philox Pharmaceuticals Ltd. with the Company has been duly sanctioned by the Honorable High Court of Gujarat at Ahmedabad on 28th July, 2005.

Bonus Equity Shares

The Company has allotted Equity Shares of Rs.5/- as Bonus Shares to the Equity Shareholders of the Company as on Record Date, 29th May, 2004 in the ratio of 1 (one) Equity Share of Rs.5 each for every 1 (one) equity share of Rs.5 each held by the equity shareholders.

Closure of Buyback offer of Company's Equity Shares

The Company has closed the Equity Shares Buyback at the end of the working hours on October 6, 2003. Under the Buyback offer, the Company has bought back 8,32,938 equity shares of Rs.5 each from the shareholders.

Buyback of the Company's Bonus 6% Cumulative Redeemable Preference Shares

The Company has bought back 14,02,61,922 number of 6% Cumulative Redeemable Preference Shares of Rs.1/- each at a price of Rs. 1.03 per Preference Share, at an aggregate amount of Rs.14,44,69,780 through Tender Offer as authorised by the Board of Directors of Company at their meeting held on 21st April, 2004.

Voluntary Delisting of Company's Equity Shares from the Stock Exchanges at Kolkata and Vadodara

The Company has received the voluntary de-listing approval from the Vadodara Stock Exchange with effect from 30th July, 2004. In case of Calcutta Stock Exchange, Kolkata the Company has complied with all the requirement for the voluntary de-listing of Equity Shares from the said Stock Exchange and as stated to them, our securities are deemed to be de-listed from the Calcutta Stock Exchange, Kolkata. The Company is pursuing the said Stock Exchange for their issuing the de-listing letter to the Company.

The division caters mainly to ENT’s, Orthopedicians & Gastroenterologists along with Neurologists, who are specifically covered to consolidate share for allied therapy (PPI, NSAID, Antidepressive). Zofer MD, the company’s first mouth dissolving ondansetron formulation was launched to a brisk uptake, and has dislodged the earlier market leader with thrice its growth rate.

Aquamet, the nasal spray mometasone formulation that we’d launched last year, has reached the top slot with ENT specialists in patients not adequately controlled with antihistamines. Gastrics and Deslor have earned strong support from ENT & chest specialists, to reach the top rank with these key prescribers of the molecule.

Among key products brought to market was the latest cox 2, Ezact, which was one of the first to reach market amongst competing brands.Depopred, one of only 2 brands available in the country, offers an alternative to Orthopedicians to treat patients chronic pains those with osteoarthritis & rheumatoid arthritis.

Customer contact programs on irritable bowel syndrome (IBS) & allergic rhinitis were also organized all over the country. International guidelines on Asthma (GINA) & COPD (GOLD) were distributed to the medical fraternity.

‘Always-on’ stress: more damaging than imagined

When we experience a stressful situation, our stress system activates a range of biological mechanisms that increase energy to help us cope. But perpetual or intense stress may harm the brain and its function. 

The preliminary examination of patients with Cushings Syndrome also indicates that severe stress harms the hippocampus and memory. These patients produce massive amounts of the stress hormone cortisol. Research also shows relationships between exceptional stress and ailments like post traumatic stress disorder.

(All images and diagrams are not included in the text. The text is a transcription of the visible content.)
Mr. Ashwin Dani was appointed as an additional Director of the Company at the Board meeting held on 28th January, 2004 and subsequently appointed as Director of the Company by the members at their Extra ordinary General Meeting held on 6th May, 2004.

Shri S. Mohanchand Dadha and Shri Sudhir V. Valia retired by rotation and were re-appointed as Directors on 30th December, 2004 when the Twelfth Annual General Meeting of the Company was convened 2001 (which has now got adjourned to 30th September, 2005).

Directors’ Responsibility Statement

Pursuant to the requirement under Section 217(2AA) of the Companies Act, 1956, with respect to Directors’ Responsibility Statement, it is hereby confirmed:

(i) That in the preparation of the annual accounts for the financial year ended 31st March, 2004, the applicable accounting standards have been followed along with proper explanation relating to material departures;

(ii) That the Directors have selected appropriate accounting policies and applied them consistently and made judgements and estimates that were reasonable and prudent so as to give a true and fair view of the state of affairs of the Company at the end of the financial year and on the profit of the Company for the year under review;

(iii) That the Directors have taken proper and sufficient care for the maintenance of adequate accounting records in accordance with the provisions of the Companies Act, 1956 for safeguarding the assets of the company and for preventing and detecting fraud and other irregularities;

(iv) That the Directors have prepared the annual accounts for the financial year ended 31st March, 2004 on a ‘going concern’ basis.

Auditors

At the Twelfth Annual General Meeting held on 30th December, 2004, the shareholders have already appointed Messrs. Deloitte Haskins Chartered Accountants, Mumbai as your Company’s auditors, in place of Messrs. Price Waterhouse, Chartered Accountants, Mumbai.

Acknowledgements

Your Directors wish to thank all stakeholders and business partners—your Company’s bankers, financial institutions, medical profession and business associates for their continued support and valuable co-operation. The Directors also wish to express their gratitude to investors for the faith that they continue to repose in the Company.

For and on behalf of the Board of Directors

DILIP S. SHANGHVI
CHAIRMAN & MANAGING DIRECTOR

Mumbai,
18th August, 2005

Management Discussion and Analysis

Highlights we’d like to begin this report with:

1. We reached number 1 slot in cardiology
2. USFDA approval for our Panoli bulk active and Halol dosage form factories
3. 2 new R&D sites and 2 manufacturing units* were commissioned

(*) in partnership

Cautionary Note

This Management discussion and analysis contains forward-looking statements. Such statements are based on management’s current expectations and are subject to a number of risks and uncertainties which could cause actual results to differ materially from those described in the forward-looking statements.

<table>
<thead>
<tr>
<th>Year</th>
<th>Gross Block</th>
<th>Net Worth</th>
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<tr>
<td>2000</td>
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<td>2004</td>
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Gross Block

Net Worth

The new R&D centre, SPARC Tandalja

(*) in partnership

Color profile: Disabled
Composite 175 lpi at 45 degrees
Industry Outlook

The pharma sector showed a 7.3% growth year on year at the end of March 2004, mirroring a strong performance of the economy and a good showing across sectors by companies. The factors we’d highlighted as impacting growth in the sector remain: the emergence of regional smaller companies, price based slowdown in the larger segments. As we’d shared earlier, while there is an increase in the competitive interest in specialty therapy areas, and much of it in the same price band, customer relationships offer us a headstart. These relationships are built on early entry into market, aggressive new product introduction, tight operational controls. Also, increasing awareness of Lifestyle ailments and the increasing pressure of daily living means that the specialty sectors will continue to grow faster than the rest of the industry. Increasing affluence, diet and lifestyle changes, the pressures of daily living-all these continue to propel specialty segment growth at above industry growth rates.

Some steps have been taken in order to create the appropriate regulatory framework for the 2005 deadline, some lack of clarity remains. A new patent act has been put into place and this year witnessed the first set of EMUs being granted, however lack of clarity on the treatment of crystal forms, polymorphs saw a product being launched and then withdrawn. Data exclusivity continues to be a contentious issue, and the issue of manufacturing under compulsory license for countries that lack basic infrastructure, persists. The new DPCO™ seems to be caught in a legal quagmire, and it is difficult to say when the new price control order would be announced.

The pharma industry, despite being impacted by a host of factors, continues to grow at a clipping pace, invest in research and make respectable inroads into international markets.

Company Performance

On a standalone basis, total income increased to Rs. 9598 million. Domestic formulations accounted for 63% of sales at Rs. 3603 mill. International markets accounted for 24% of sales, export formulations accounted for 8.8% sales.

On a consolidated basis, total income increased to Rs. 9995 million, up 9.84%. Domestic market was 63.5% of sales at Rs. 6738.5 mill. (Caraco’s sales in its home market of the US accounts as export sales). International markets accounted for 36.4% of sales.

Strong customer relationships and a distinct specialty focus continues to be the reason we grow faster than industry, and we are trying to put the same thought process to work in international markets too. We’ve also tried to apply this focus in areas that are as diverse as research and generic markets. This focused approach of working has earned us good results in the past.

Human Resources

Growth from Team Sun Pharma is the resultant endeavor of a relentless team comprising a workforce of over 4000. As always, Human Resources continues to fuel employee growth and potential through newer training and development initiatives. A facilitating and highly engaging work environment greatly affords internal opportunities to learn and grow. Your company’s Human Resources especially maintains its efforts in attracting and retaining the best talent.

Your directors acknowledge the contribution of your company’s human capital, and due thanks are in order for Team Sun Pharma.

Information as per Section 217(2)(A) of the Companies Act, 1956, read with the Companies (Particulars of Employees) Rules, 1975 as amended, is available at the registered office of your company. As per the provisions of Section 219(1)(b)(iv) of the said Act, the Report and Accounts are being sent to all shareholders of the Company excluding the statement of particulars of employees u/s 217(2A) of the said Act. Any shareholder interested in obtaining a copy of this statement may write to the Company Secretary at the Corporate office of the Company.

Additional Information

The additional information pursuant to Section 217(1)(za) of the Companies Act 1956 read with the Companies (Disclosure of Particulars in the Report of the Board of Directors) Rules, 1988, is given in Annexure and forms part of this report.

Corporate Governance

Certificate dated 18th August, 2005 of the auditors of your Company regarding compliance of the conditions of Corporate Governance as stipulated in Clause 49 of the listing agreement with stock exchanges, is enclosed.

Consolidated Accounts

In accordance with the requirements of Accounting Standard AS-21 prescribed by the Institute of Chartered Accountants of India, the Consolidated Accounts of the Company and its subsidiaries is annexed to this Report.

Finance

All the banks in consortium continue to offer their highest rating to your company enabling it to source funds from banks at the finest rate of interest. CRISIL continued to reaffirm their highest rating of “PI +”, for your Company’s Commercial Paper Program throughout the year.

The Company does not offer any Fixed Deposit schemes.
Research and Development

Early this year, i.e 2004, one NCE (or new molecule) entered human trials in Europe; our expectation is that 2 NDDS (or novel drug delivery systems) will enter human trials over the next few months. This is perhaps the best validation of the energy and investments we have been making in R&D, and a reassurance that we are moving in the right direction. Cumulative investment in R&D now exceed Rs.2934 mil. of which we spent Rs.1077 mil. this year.

We began using 2 more R&D sites, this move offers 250,000 sq. ft of research floor area, and we expect to take the scientific staff to over 500 in the next 2 years. Currently of our scientific staff of over 400 people, about 80 are directly involved in innovative projects both in drug discovery and platform technology. In the domestic market, a number of interesting new products developed at SPARC were launched; 21 were combinations / delivery systems based / technically complex products (as always, we do not include line extensions unless there is a delivery technique used). 16 bulk actives were scaled up based on processes developed in house (list attached).

As I’ve said earlier, in the short term projects we’ve had considerable success with reverse engineered projects both in dosage form and bulk active process development. This is the first year I have progress to report with the medium / long terms project with developments on the NCE & NDDS front to share.

As we continue to ramp up revenue research spend from 4.09% to at an estimated 5.71% for Sun standalone, the investments, time frames and risks associated with such projects would also increase.

The NDDS projects we are pursuing in DPIs, CR/SR, biodegradable membranes and targeted delivery systems continue on track.

On both the NCE & NDDS projects, I am aware that the information we are sharing may be viewed as inadequate, but till the requisite intellectual property is in place and we reach a greater stage of confidence, we’d seek your patient understanding. The pace of filing patents to protect intellectual property continues, 321 patents filed, 33 granted.

Our emphasis continues to be work that is international in scale and scope and we are willing to invest sums that are larger than usual if we see a need / requirement even if this affects the profit in the short term. We believe we need to make these investments in research and in international markets in order to take Sun Pharma to the next phase of its growth.

Domestic market performance:

As per the IMS-ORG Retail Store Audit for March 2004, we closed the year at 5th rank, the 5th successive year at this position. We grew 12.5% vs 7.3% for the sector. Market share in July was at 3.15%, up from 2.99% last year. About 150 brands rank among the top 3 by molecule.

New products introduced this year accounted for less than 1% of domestic formulation sales, those introduced in the last 3 years accounted for 28%. As we’ve said earlier, specialty prescriptions typically build over time, and are sticky- since a patient would not be quickly shifted from a prescription that he is stable on.

2 new manufacturing sites*

CMARC

We continued to show a good performance in our core specialty areas with a top 3 ranking in those therapy areas that account for over 70% of our current domestic business. Of critical significance was the rank increase in cardiology, where several years of effort have now brought us to number 1. In gynecology, oncology we continued to make significant inroads with ranks among the top 10 from those in the 30s when we first entered these areas in 1997. Our plan of making 1 or 2 key tech based products that can form a hook for the rest of the product range seems to be working well, and several more products in our development pipeline will help us build on this strategy.

Progress on new manufacturing site:

Last year we’d shared that the groundwork had begun for 2 new manufacturing sites* at Jammu and Dadra, essentially to address the domestic market. Both these plants are new operational. These plants were formed in partnership between Sun Pharma and Sun Pharma Key Employees Benefit Trust. During the course of the year, a massive expansion plan at Panoli was begun, which on completion will add 130 KL capacity over 270,000 sq. ft. in 2 phases.

US Markets

The most significant parameter of Indian companies intent for the US markets is the number of DMF filings from Indian companies with the USFDA. This first half the number of Indian filings made was 74, or 30% of all global filings, making the country the largest potential supplier of bulk actives to the US. The USFDA is close to starting a fully equipped office in Delhi, and competition from Indian companies has begun getting mentioned in industry reports and news articles. I had earlier highlighted how the uniquely Indian opportunity, building on strong process chemistry, a good understanding of patents with a keenness to learn, low cost product development, good bulk manufacturing facilities...
As we take ahead our US plans, I believe this is the time to move on to the next growth orbit, and we continue to seek an opportunity to acquire a generic business or brands in the US. In line with our philosophy on acquisitions, we’d look for an opportunity where a connection can be made and both can benefit from the synergies of growth. I expect to have more to share on this aspect, going ahead.

**International Markets**

**Dosage forms**

With sales of Rs. 609 mill, we continue to be excited by the international branded product markets (ex-US). In markets across South East Asia, Africa, Russia & China we have a priority list of 30 brands; a 249 person strong field force; and marketing activities and control systems that are similar to those we have in India. The slow & steady approach to brand building with a doctors list, regular call coverage and innovative branding programs in competitive markets, continues to help us earn prescriptions. This year operations in three important markets: Brazil, Mexico & Bangladesh moved to the next phase with products cleared. In Bangladesh, a market where we have been present for a decade now, we move to the next phase with a plant just commissioned which will allow for a more active participation. I should have more to share about these markets going ahead.

**Bulk Actives**

In recognition of the fact that the bulk active market is that of falling margins, at Sun we’ve tried to focus on the higher end of the business with specialty bulk actives. This year we added capacity in dedicated manufacturing sites that concentrate on higher end specialty bulk actives such as steroids, oncologicals, sex hormones, and peptides. Our Panoli factory received USFDA approval; it already holds European and Australian approvals. With Ahmednagar, which has held USFDA approval for over two years now, this facility gives us the flexibility to manage production schedules across 2 sites and handle different products and batch sizes.

In all, across sites, we have 12 DMFs and COS approved and 15 more filings awaiting approvals.

As we continue with our focus on regulated markets, seek customers that offer a tie in opportunity for the long term and sell tonnage that offers higher value, we expect the bulk active part of our business to continue adding robust turnover.

At the close of the year, an entry was also made in the higher end of the 2nd and 3rd generation cephalosporin business with the proposed acquisition of Phlox Pharma. Phlox offers us a low cost entry opportunity in the regulatory market space for these products with a minimal capex; and I expect to share details of our filings in due course.
perhaps the most important of all, experience in India and markets like India has offered us a head start in the US market. During the course of the year, companies built on this advantage, and the reverse process has also begun with US and European companies recognizing the advantage of an Indian presence.

The $16.2 billion market for generics in the US grew about 21% between 1999 and 2001. On account of regulatory measures and patent expiries, the market is expected to grow to $31 billion in 2006, an annual growth rate of 14% (Scrip Magazine, March 2003). This market, already incredibly complex, added a few layers of complexity with the emergence of authorized generics, continuing mergers/acquisition in the generic space and a few unanticipated legal decisions on patent challenges. The generic market is lucrative and rewarding for the well prepared and requires extensive preparation for companies that seek to participate. Indian companies recognize this and are gearing up to address this complexity.

Caraco, our US subsidiary continued on a growth path this year too.

For December 2003, Caraco had sales of $45 million (up from $22 million the previous year), a number higher than its guidance of $42 million. For the first half of 2004, Caraco had sales of $28 million and a loss of $0.7 million, after an R&D charge related to product transfer of $12.6 million. Earlier in 2004, we had increased stake to 63% on the buyout of equity from 3 large shareholders. As has been shared earlier, under the terms of the agreement, for each product transfer Sun Global receives 544,000 shares of preferred stock convertible into shares after 3 years on a 1:1 basis.

Caraco has 14 ANDAs approved and marketed, 4 more filings awaiting approval. 17 products in 33 strengths and 78 pack sizes are being marketed, primarily to large drug wholesalers, buying groups and government agencies. Caraco has shared guidance of 20-25% sales growth for the year, and expects to make 7 ANDA filings in 2004.

Starting this year, Sun Pharma also commenced with filings from an Indian site, with 5 filings at the close of March 2004. A clear selection criteria distinguishes the products selected for Caraco and those for India. Given our conservative attitude to risk, only 1 or 2 of the filings we make would address a para 4 opportunity.

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R&D spend of Rs. 1077 million

321 patents filed

Research and Development

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I had earlier highlighted how the uniquely Indian opportunity, building on strong process chemistry; a good understanding of patents with a keenness to learn, low cost product development; good bulk manufacturing facilities and immediate service to the regulatory body, will open the doors to the US market. This expectation to a large extent has been fulfilled, with 2 new companies entering the US recently.

3.15% market share, higher than industry GR.

(* in partnership)
Industry Outlook

The pharma sector showed a 7.3% growth year on year at the end of March 2004, mirroring a strong performance of the economy and a good showing across sectors by companies. The factors we’d highlighted as impacting growth in the sector remain: the emergence of regional/s smaller companies, price based slowdown in the larger segments.

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Your directors acknowledge the contribution of your company’s human capital, and due thanks are in order for Team Sun Pharma.

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In accordance with the requirements of Accounting Standard AS-21 prescribed by the Institute of Chartered Accountants of India, the Consolidated Accounts of the Company and its subsidiaries is annexed to this Report.

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The Company does not offer any Fixed Deposit schemes.
Mr. Ashwin Dani was appointed as an additional Director of the Company at the Board meeting held on 28th January, 2004 and subsequently appointed as Director of the Company by the members at their Extra ordinary General Meeting held on 6th May, 2004.

Shri S. Mohanchand Dadha and Shri Sudhir V. Valla retired by rotation and were re-appointed as Directors on 30th December, 2004 when the Twelfth Annual General Meeting of the Company was convened 2001 (which has now got adjourned to 30th September, 2005).

**Directors’ Responsibility Statement**

Pursuant to the requirement under Section 217(2AA) of the Companies Act, 1956, with respect to Directors’ Responsibility Statement, it is hereby confirmed:

(i) That in the preparation of the annual accounts for the financial year ended 31st March, 2004, the applicable accounting standards have been followed along with proper explanation relating to material departures;

(ii) That the Directors have selected appropriate accounting policies and applied them consistently and made judgements and estimates that were reasonable and prudent so as to give a true and fair view of the state of affairs of the Company at the end of the financial year and on the profit of the Company for the year under review;

(iii) That the Directors have taken proper and sufficient care for the maintenance of adequate accounting records in accordance with the provisions of the Companies Act, 1956 for safeguarding the assets of the company and for preventing and detecting fraud and other irregularities;

(iv) That the Directors have prepared the annual accounts for the financial year ended 31st March, 2004 on a ‘going concern’ basis.

**Auditors**

At the Twelfth Annual General Meeting held on 30th December, 2004, the shareholders have already appointed Messrs. Deloitte Haskins Chartered Accountants, Mumbai as your Company’s auditors, in place of Messrs. Price Waterhouse, Chartered Accountants, Mumbai.

**Acknowledgements**

Your Directors wish to thank all stakeholders and business partners-your Company’s bankers, financial institutions, medical profession and business associates for their continued support and valuable co-operation. The Directors also wish to express their gratitude to investors for the faith that they continue to repose in the Company.

For and on behalf of the Board of Directors

DILIP S. SHANGHVI
CHAIRMAN & MANAGING DIRECTOR

Mumbai, 18th August, 2005

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**Management Discussion and Analysis**

Highlights we’d like to begin this report with:

1. **We reached number 1 slot in cardiology**

2. **USFDA approval for our Panoli bulk active and Halol dosage form factories**

3. **2 new R&D sites and 2 manufacturing units* were commissioned**

(* in partnership)

Cautionary Note

This Management discussion and analysis contains forward-looking statements. Such statements are based on management’s current expectations and are subject to a number of risks and uncertainties which could cause actual results to differ materially from those described in the forward-looking statements.

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**2 new R&D sites and 2 manufacturing units**

The new R&D centre, SPARC Taldeja