IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., et al., Plaintiffs, v. COBALT LABORATORIES INC., et al., Defendants.	C.A. No. 08-021 (GMS) (LPS) CONSOLIDATED **REDACTED VERSION**
FOREST LABORATORIES, INC., et al., Plaintiffs, v. BARR LABORATORIES, INC., et al., Defendants.	C.A. No. 08-022 (GMS) (LPS)
FOREST LABORATORIES, INC., et al., Plaintiffs, v. DR. REDDY'S LABORATORIES, INC., et al., Defendants.	C.A. No. 08-052 (GMS) (LPS)
FOREST LABORATORIES, INC., et al., Plaintiffs, v. ORGENUS PHARMA INC., Defendant.	C.A. No. 08-291 (GMS) (LPS)

FOREST LABORATORIES, INC., et al.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 08-336 (GMS) (LPS)
APOTEX INC., et al.,	)	
Defendants.	)	

APPENDIX (VOLUME II OF II) TO PLAINTIFFS' ANSWERING BRIEF IN OPPOSITION TO DEFENDANT ORCHID INDIA'S MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION

AND

OPENING BRIEF IN SUPPORT OF THEIR CONTINGENT CROSS-MOTION TO TRANSFER

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CERTIFICATE OF SERVICE

I hereby certify that on July 3, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:.

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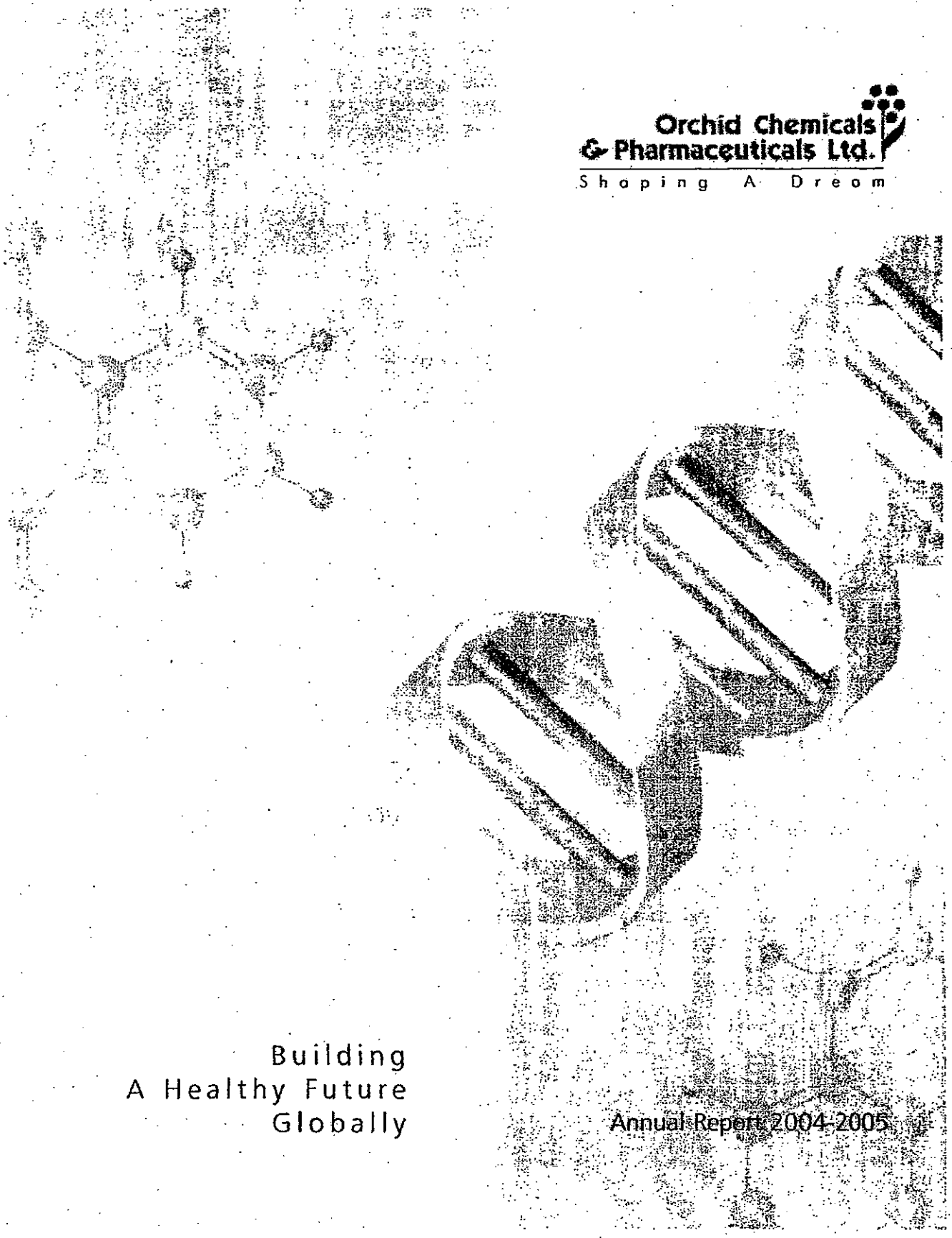
EXHIBIT 6

Orchid Chemicals & Pharmaceuticals Ltd.

Shaping A Dream



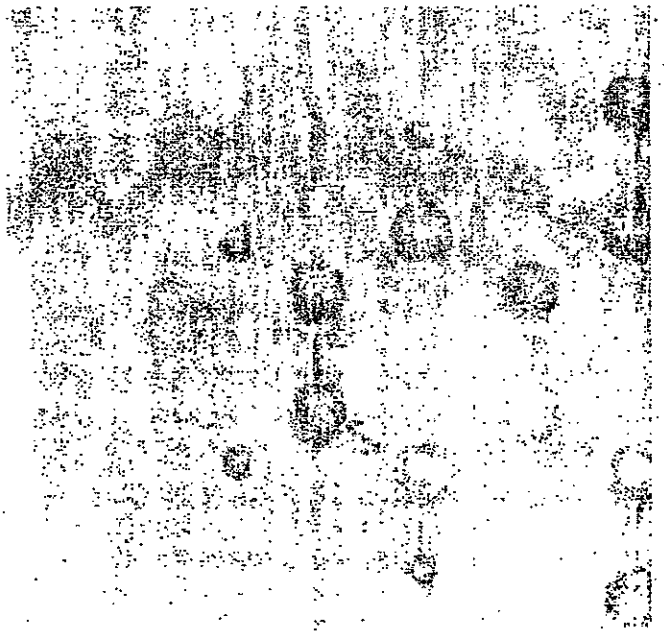
Building A Healthy Future Globally

Annual Report 2004-2005

OCP00000350



Forward-looking statement » This annual report includes forward-looking statements and projections, which are based on our current expectations and forecasts about future events. Such statements involve known and unknown risks, uncertainties and other factors that may cause and differ the actual results materially. Such factors include, but are not limited to, changes in local and global economic conditions, our ability to successfully implement our strategies, the market acceptance of and demand for our products and services, our growth rates and expansion, technological change and our exposure to market risks. By this nature, these expectations and projections are only estimates [illegible] could differ from these in the future.



Nurturing Life

Orchid has been a major force in the development and manufacturing of cepholosporin antibiotics in India, with a leading market position globally. Orchid has since moved up the healthcare value chain by supplementing its core bulk drug capabilities with finished dosage form competencies and drug discovery programmes.

Orchid is extending its leadership position to the other life saving anti-infective products on one hand and making a fast-track entry into life-style management drugs on the other.

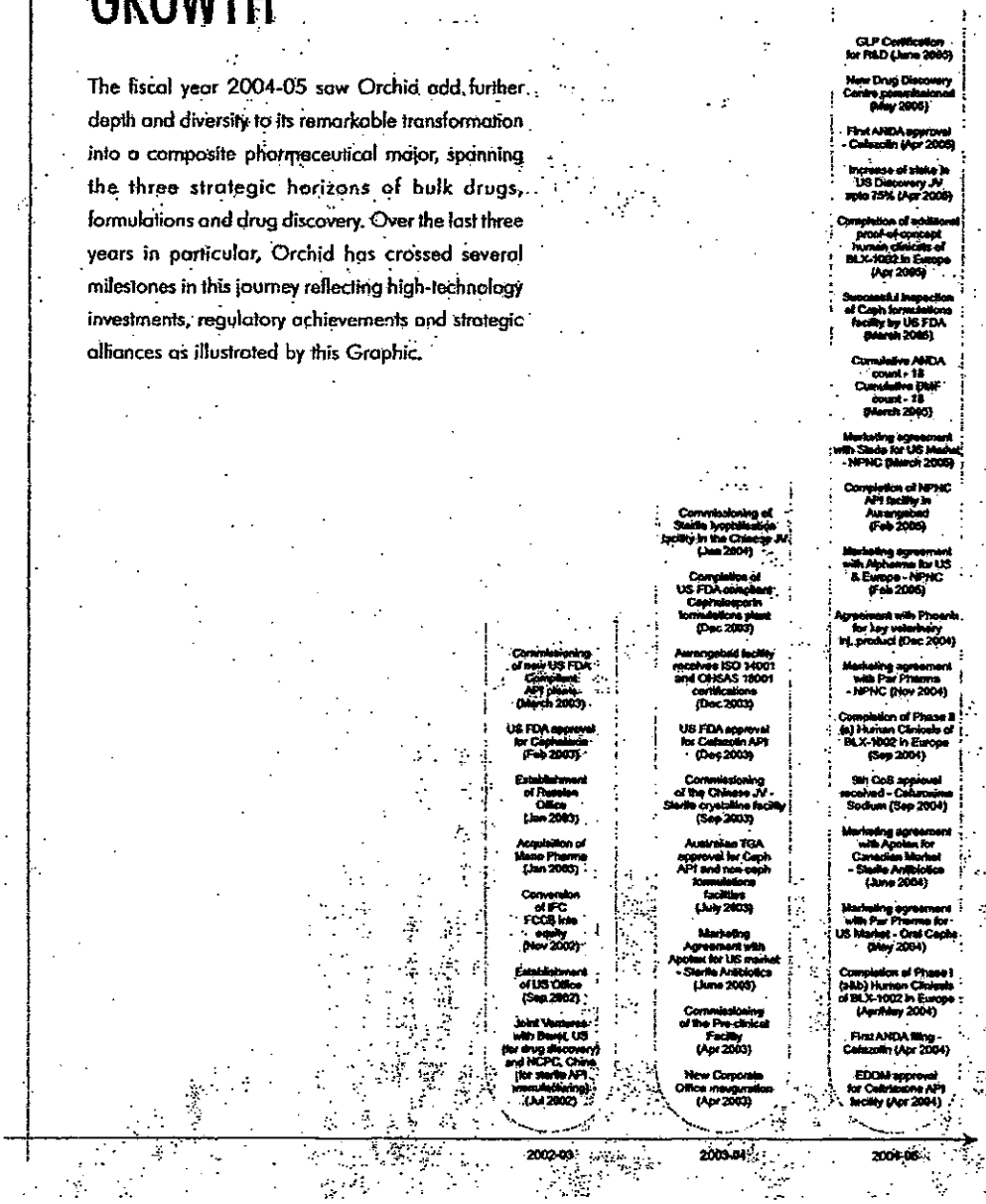
With a vastly increased and diversified product portfolio, versatile and eco-friendly manufacturing capabilities and wide ranging distribution arrangements in developed as well as developing countries, Orchid is set to play a major role in global healthcare, nurturing life and bringing good health and hope for the mankind.

Vision

Become a composite and meaningfully integrated pharmaceutical corporation competing in differentiated arenas where greater, more sustainable value can be created

TRANSFORMATIONAL GROWTH

The fiscal year 2004-05 saw Orchid add further depth and diversity to its remarkable transformation into a composite pharmaceutical major, spanning the three strategic horizons of bulk drugs, formulations and drug discovery. Over the last three years in particular, Orchid has crossed several milestones in this journey reflecting high-technology investments, regulatory achievements and strategic alliances as illustrated by this Graphic.



Orchid Chemicals & Pharmaceuticals Ltd.

A diversified bulk drugs capability

Orchid's core competencies in active pharmaceutical ingredients (APIs) constitute the foundation of Orchid's growth and competitiveness. As a manufacturer of several cephalosporin antibiotics covering all the four generations, Orchid has an undisputed leadership position in the global markets. Orchid is now poised to extend its leadership in the cephalosporin API field to a much wider anti-infectives portfolio on one hand and a well-diversified non-antibiotic product arena on the other hand.

Expanding product portfolio

Orchid's wider antibiotics portfolio now covers, besides cephalosporins, high-end betalactams, monobactams and carbapenems. The wide product range further reinforces Orchid's dominant position in the anti-infective medicines business. Orchid's more recent non-antibiotic product portfolio covers drugs in central nervous system, cardio-vascular, gastro-intestinal, pain management and osteoporosis therapeutic categories, to name a few. Taken together, Orchid has now a significantly diversified bulk drugs portfolio which can support finished dosage forms for a wide range of therapeutic solutions.

Manufacturing versatility

Orchid's two major manufacturing complexes at Alathur, near Chennai and Aurangabad are equipped to produce a wide range of antibiotic and non-antibiotic APIs, besides certain active nutraceutical ingredients in dedicated facilities.

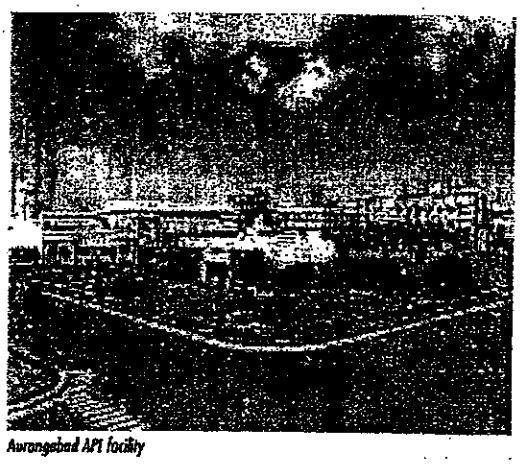
Orchid's cephalosporin API manufacturing facilities at Alathur are US FDA approved for oral and sterile cephalosporin production. Various products from these facilities have Certificates of Suitability from the European Directorate of Quality for Medicines (EDQM). Exports of select APIs to the US have begun during the year under review and are expected to gather momentum during this fiscal, supplementing the ongoing exports of APIs to other regulated markets such as Europe.



Cephalosporin API facility, Alathur

Orchid's API complex at Aurangabad is fast developing into a new state-of-the-art hub for bulk drugs production. It has two separate facilities for production of betalactam and non-betalactam APIs. The betalactam facility has been validated for US FDA compliance leading to the planned submission of Drug Master Files this fiscal. During the last quarter of 2004-05, Orchid has also established at Aurangabad a new facility for manufacture of non-antibiotic APIs, designed for US FDA compliance. The plant, now validated, is engaged in manufacture of exhibit batches and filing of Drug Master Files (DMFs) for several APIs in the non-penicillin, non-cephalosporins space.

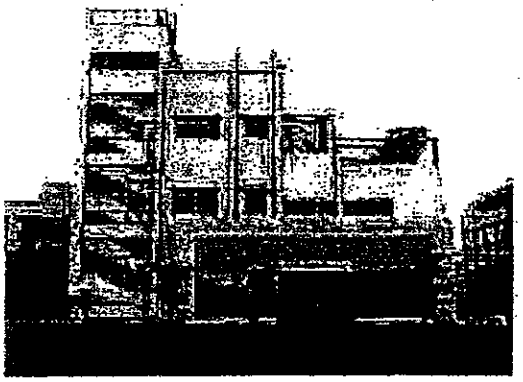
Orchid's API infrastructure is thus now more versatile and better-equipped to power the contemplated multi-therapeutic generics thrust, with a particular focus on the US and European markets.



Aurangabad API facility



Non-penicillin, non-cephalosporin API facility, Aurangabad



Betalactam API facility, Aurangabad

A broad-spectrum entry into regulated generics

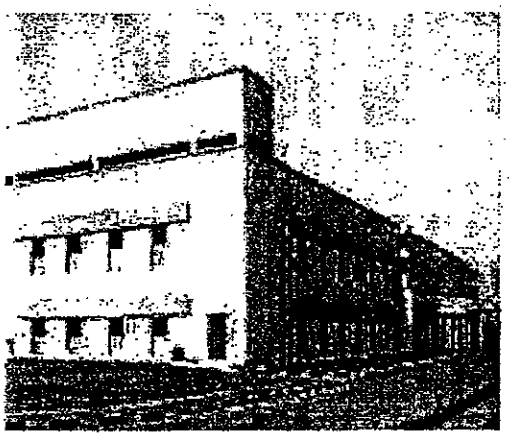
Orchid has been implementing on a fast-track basis, a strategy of developing the generics business in regulated markets, with a special emphasis on US generics. Starting initially with oral and sterile cephalosporins, the scope has been expanded to include high-end betalactam injectables and oral non-penicillin, non-cephalosporin products.

Successful US FDA inspection

During the year under review, impressive progress has been made in terms of establishing additional infrastructure and reinforcing organizational capabilities in the finished dosage forms business, leading to regulatory approvals and furthering product-market scope.

The newly established state-of-the-art formulations facility at Irungattukottai near Chennai has emerged as a major driver of the regulated market business for the future. The first Abbreviated New Drug Application (ANDA) for Cefazolin was filed on April 29, 2004 from the cepholosporins facility. Thereafter, during the fiscal under review several ANDA filings were made, taking Orchid's total count of ANDA filings during the year to 18. Orchid has emerged as a top filer of ANDAs in the Indian pharmaceutical industry in the very first year of its generic dosage forms activity. Orchid's track record of ANDA development and filing, all undertaken organically in-house, is unparalleled as a first year performance of US FDA compliant regulatory operations by any generics company in India, and most probably in the world.

Orchid's finished dosage form facility for cephalosporins has had a successful inspection by US FDA in March 2005



Cephalosporin generic formulations facility, Irungattukottai, Chennai

without any '483' observation. The FDA review covered nine ANDAs and all the dosage forms viz., sterile injectables, oral tablets, oral capsules and oral dry syrups. Subsequent to the US FDA inspection, Orchid received in April 2005 the formal US FDA approval for Cefazolin generic injectable product. The approval covers 500mg/vial and 1 gm/vial dosage strengths. Approval for Ceftrioxone injectable generic product in 500mg/vial and 1 gm/vial dosage strengths as also other speciality packs would follow. These are significant milestones for the US generics business, paving the way for commercial launch of generic cephalosporin dosage forms into the US market.

Approvals for the other ANDAs that were reviewed in the US FDA inspection process (as also those in the queue) are also expected to be received in a progressive manner going forward. These include products which are yet to go off-patent, mature generics as well as niche generics, supporting a broad-based thrust in the US generics markets.



State-of-the-art sterile vial line, Generics facility

Orchid Chemicals & Pharmaceuticals Ltd.



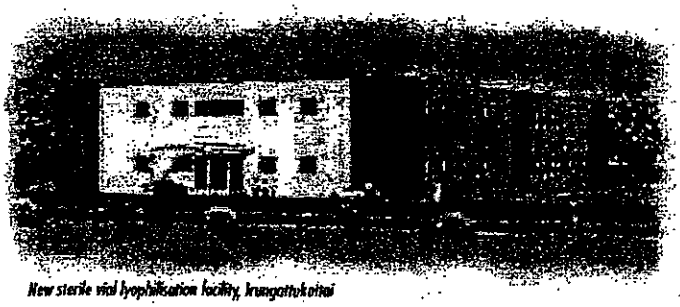
High-speed capsule filling, Generics facility



Sterile powder filling, Generics facility

Expanding generics footprint

The infrastructure and the skill-sets in the generics business are being further expanded to drive a larger multi-therapeutic strategy, with a singular focus on regulated markets. Leading the new wave of development are a state-of-the-art vial lyophilisation facility for betalactams and a modern oral dosage form facility for a wide range of multi-therapeutic, essentially non-antibiotic, products. Both the facilities will be ready to file ANDAs from the second half of the current fiscal. An additional low-volume injectable vial line has been added in the cephalosporins plant to cater to the needs of emerging markets such as Brazil and Russia which present varied and specific needs.

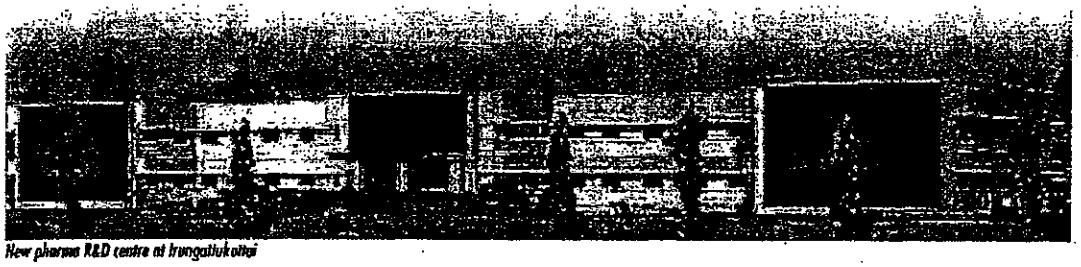


New sterile vial lyophilisation facility, Irungattukottai

The generics effort is further reinforced with the establishment of a new expanded pharmaceutical R&D facility contiguous to the formulations complex. This new research block has several GLP compliant development and analytical laboratories, which will provide the requisite boost to general formulations development, ANDA development for generics markets and research in novel drug delivery systems, with significant additional space for further expansion and diversification of research activities.

The track record of aggressive regulatory filings in the cephalosporin finished dosage forms would be maintained, while a slew of regulatory filings for certain other therapeutic formulations would be added. A doubling of regulatory filings in the overall is on cards in fiscal 2005-06.

Simultaneous with the US-centric regulatory thrust, inspection of the dosage forms facilities by European and other major international regulatory agencies is being triggered. A broader registration road map for other large volume markets has been drawn up. The focus in 2005-06 would be on spreading the registration foot-print across European and other potential markets.



New pharma R&D centre at Irungattukottai

New trajectories of growth



Ceftrioxone generic products for US

Orchid is set to move into higher trajectories of growth in revenues and profits based on the API diversification and the broad-based generics programmes it has on hand. The first wave of growth would commence in the near-term based on the cephalosporin based foray from mid-2005 while simultaneous progress on different niche categories of antibiotics on one hand and a host of non-antibiotic products on the other would lead to a further wave of growth from mid-2007.

Orchid has marketing alliances with Apotex and Par of USA for marketing eight injectable antibiotics and seven oral cephalosporins respectively in various dosage forms. In addition, Orchid has a marketing alliance with Phoenix of USA (now part of IVAX Group and called IVX Animal Health, Inc.) for a unique veterinary cephalosporin injectable dosage form in the US. The current combined US retail market size of these 16 products is USD 3.25 billion. Of these, 6 products yet to go off patent or are yet to be genericised constitute a lion's shore of USD 2.2 billion. The current retail market size in the EU for these 16 products is close to USD 2 billion, marking a significant incremental opportunity.

Orchid's foray in the US cephalosporin space is set to yield early dividends as the initial generic introductions would correspond to two blockbuster products currently under patent viz., Ceftrioxone injection and Cefprozil oral tablet which would go off patent in July 2005 and December 2005 respectively. These two products have a current combined retail market of over USD 1 billion, providing an attractive initial entry platform. This launch would be supplemented with other product introductions, progressively covering all the sterile and oral cephalosporin generic products.

The cephalosporin industry is characterized by relatively high entry barriers, requiring as it does complex chemistry and technology-intensive, dedicated manufacturing facilities. The markets, therefore, have a relatively limited pipeline of competitive regulatory approvals. Orchid, with its wide range of products covering all the four generations, an end-to-end connectivity from API to formulations, a robust regulatory track record and broad-spectrum marketing alliances is well-positioned to capture the generics market opportunity. Orchid expects a major boost to revenues and profits from this fiscal onwards, based on the cephalosporins generics, followed by select high-end betalactams and other anti-infectives in subsequent years.

In addition, the proposed entry into diverse therapeutic segments will provide Orchid with an even larger market canvas to address. Orchid has developed a strategic product portfolio which covers a vast array of potential generic products and has already proactively entered into marketing alliances in respect of 20 products from the master list which present early phase opportunities. The current retail market for the 20 products covered by such alliances aggregates to USD 20 billion in US and Europe together. Although the number of players in the non-cephalosporin generics field would be higher than that encountered in the cephalosporin field, the alliances already in place with established top-rung generic players such as Alpharma, Par and Stada are expected to support an effective market presence in the multi-therapeutic generics space as well. Continued addition of generic products based on strategic product selections would ensure a growing revenue opportunity.

Leveraging the emerging markets

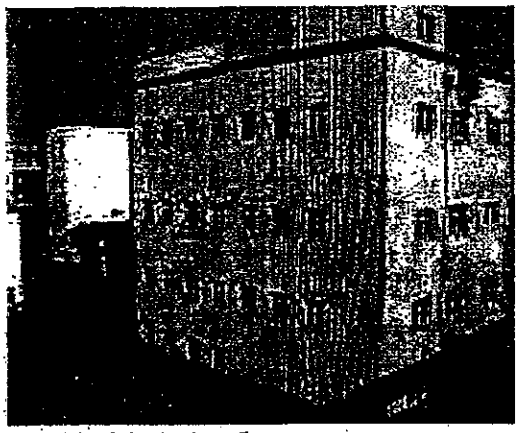
Orchid's base business in the less regulated and emerging markets continues to provide a solid foundation for the transformational growth of the Company.

Robust position in China

China continues to be a major market for the Company's APIs both in terms of direct exports and the fast-expanding operations of the joint venture, NCPC-Orchid Pharmaceuticals Limited. Revenues from China and Far East contributed 35 percent of the total revenues. Given the huge market for cephalosporin drugs in China, Orchid would continue to reinforce its presence through direct exports as well as through the joint venture.

With NCPC-Orchid completely coming on stream, Orchid has now a significantly higher global annual capacity of APIs and intermediates, of which over 40% is in the technologically challenging sterile cephalosporin space.

Orchid Chemicals & Pharmaceuticals Ltd.



NCPC-Orchid API facility, Shijiazhuang, China

During the fiscal under review, which constitutes the first full year of operations, NCPC-Orchid achieved an impressive sale of USD 20 million. Introduction of high technology, premium products with technical assistance from Orchid has helped the joint venture achieve a pre-eminent position in this class of products in China in a short span of time.

Newer markets for APIs notably, Russia, Brazil and Middle East are being consolidated further to spread the business equitably across the globe. Exports to regions other than China and US/EU posted an increase of 30 percent during the fiscal under review.

Branded formulations set to grow

In terms of branded formulations business, India continues to be an important part of the market structure for Orchid. The domestic market for formulations has been adversely impacted during 2004-05 for all pharmaceutical companies including Orchid due to the considerable de-stocking resorted to by the wholesalers and stockists in the wake of the proposed introduction of Value Added Tax (VAT). The outlook during the current fiscal is promising to be significantly better.

With the advent of product patent regime, emphasis in the domestic market will shift to consolidation of product portfolios, management of product life cycles, better market penetration and enhanced sales force productivity. Orchid is proactively equipping its field force to meet these challenges, while being alert to new product opportunities that could address therapeutic gaps in the five core therapeutic areas it operates viz., antibiotics, neuro-psychiatry, cardio-vascular, diabetes and nutraceuticals.

During the year, Orchid introduced Meropenem as a new life-saving antibiotic under the brand name of Meromer in the domestic market, leveraging Orchid's unique position as the only manufacturer in India of the bulk active. Orchid has, in addition, partnered select pharmaceutical companies in the supply and co-marketing of this premium formulation. Apart from newer cardio-vascular and neuro-psychiatry drugs, Orchid has introduced additional product combinations and extended release versions as well as novel nutritional supplements. For the current fiscal, new product plans which are not in conflict with the product patent regime are under execution to strengthen the domestic product portfolio further. Niche therapies such as dual acting anti-depressants and focused therapies for epilepsy, alzheimer's disease, hypertension and hyper-dislipidemia are planned to strengthen the product portfolio for the domestic market.

On the export front, Orchid has drawn up major plans for consolidating its presence in Russia & CIS and in the Afro-Asian countries. With two oral dosage form plants (cephalosporins and non-cephalosporins) dedicated to the emerging markets backed by sterile dosage form supplies from the US FDA compliant formulations plant, exports of branded formulations are set to increase significantly in future.

Russia & CIS would emerge as a major hub for driving the future branded formulations business. While Orchid's core cephalosporin products would be the primary growth driver, considerable potential could be harnessed from the company's unique nutraceutical range, hitherto confined to domestic markets. Organisational and field presence in the Russian and CIS regions is being strengthened in line with the perceived potential.

Fourteen countries in the regions of East Africa, West Africa, Far East and Asia have also been chosen for a dedicated marketing thrust. While over 100 products have been registered and 36 are awaiting approval, over 80 new registrations are planned this fiscal to make a major impact in these markets. A blend of exclusive and non-exclusive field force strategies would be adopted to achieve market penetration with cost-efficiency.

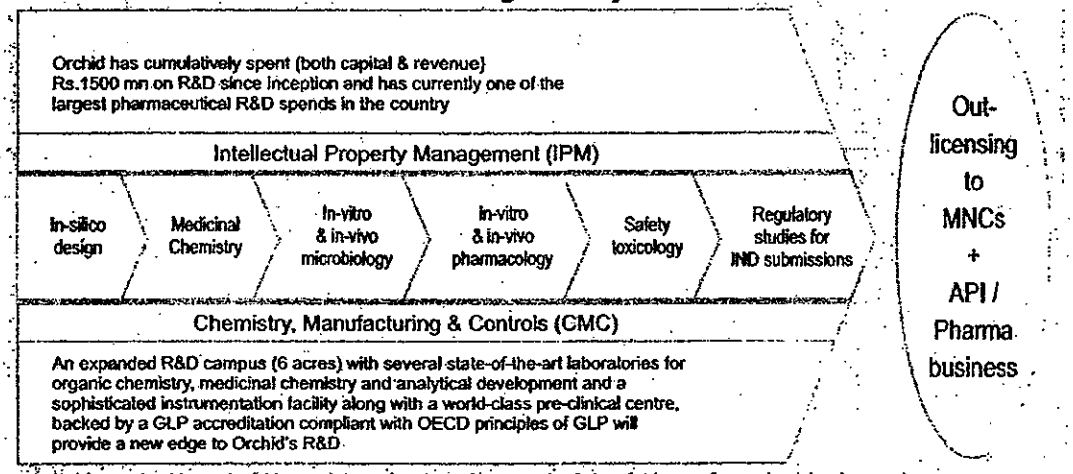


Orchid's new life-saving antibiotic Meropenem (brand name – Meromer)

Drug Discovery & Development

Orchid has an ambitious, multi-pronged drug discovery programme. Orchid's drug discovery and drug development capabilities, like the other strategic initiatives, are end-to-end connected to provide complete control and flexibility over the design, execution and management of each discovery project, as the Graphic illustrates.

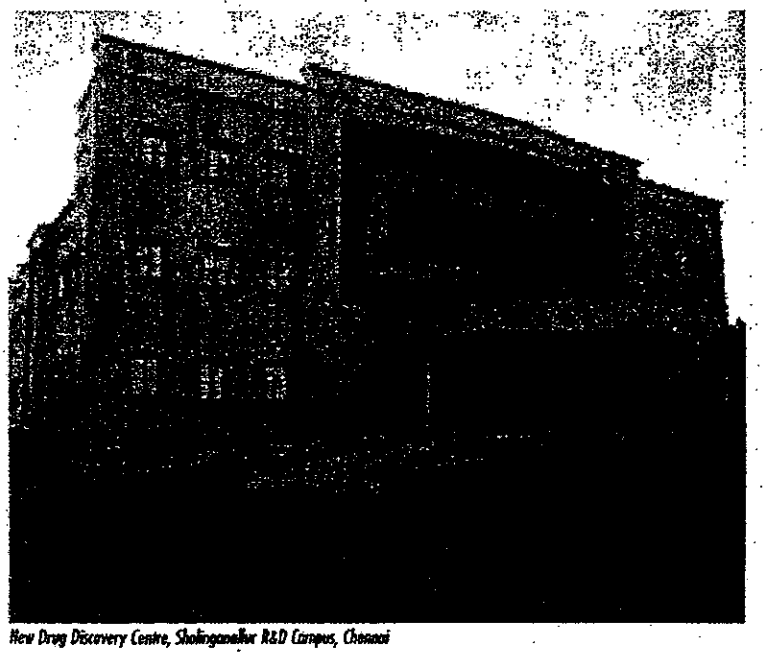
Orchid's end-to-end business model for drug discovery



Orchid has complete in-house capabilities for drug discovery and development; from structure design and compound synthesis to drug screening and drug evaluation in animal models; human clinicals are outsourced to CROs.

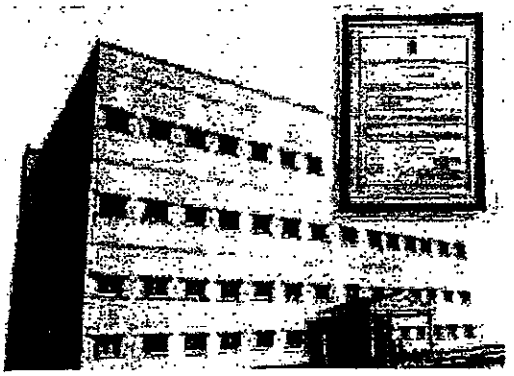
World-class infrastructure

To reinforce its drug discovery capabilities, Orchid has commissioned a new Drug Discovery Centre in the first quarter of the current fiscal at the Sholinganallur R&D campus. The modern research centre has several well-equipped laboratories for medicinal chemistry and analytical development with well-controlled atmospheric conditions and separate corridors for movement of men and materials. In line with Orchid's policy of caring for its employees and environment, each of the work stations is equipped with an individual fume hood, all of them linked and managed by a state-of-the-art scrubber system. The laboratories are supported by scientifically designed documentation control and



New Drug Discovery Centre, Sholinganallur R&D Campus, Chennai

Orchid Chemicals & Pharmaceuticals Ltd.



GLP accredited pre-clinical facility, Shokaganallur R&D Campus

archival systems to ensure knowledge management as well as regulatory compliance.

Orchid's modern pre-clinical facility which meets global standards in pre-clinical evaluation of new chemical entities (NCEs) has undertaken a wide range of activities during the fiscal year under review. The studies included world-class regulatory toxicity studies which are required for filing of Investigational New Drug (IND) Applications. A number of new screening facilities and biological evaluation models have been set up to support the drug discovery and development process.

GLP certification

Orchid's Research & Development (R&D) has received the Good Laboratory Practices (GLP) certification from the National GLP Monitoring Authority of India in June 2005. The GLP certification for Orchid's R&D covers the areas of physical-chemical testing, safety pharmacology & pharmacokinetic studies, toxicity studies, mutagenicity studies and analytical & clinical chemistry testing. The certification is granted after a detailed inspection of the facilities by the authorities and a review by the technical committee. The certification is in accordance with OECD (Organisation for Economic Cooperation and Development) Principles for GLP certification with which India's National GLP Compliance Monitoring Authority of the Department of Science & Technology is aligned with. This certification will provide further impetus to Orchid's ongoing new drug discovery (NDD) research programmes.

Orchid's chemistry capabilities are being further channeled to support the CMC requirements of new drug discovery. During the current fiscal, a new process validation laboratory with cGMP compliance will be completed in the R&D campus to enable optimization and upscaling of processes. This facility would also be an invaluable aid for 'hazop' studies.

Orchid now combines the unique attributes of a GLP accredited global contract research organisation (CRO) with the knowledge and expertise of discovering and developing new drugs from concept to delivery. Orchid's ability to partner global firms in the areas of drug discovery and drug development is further reinforced by the recent achievements and ongoing initiatives.

Orchid-Bexel NCE programmes

During this fiscal, Orchid's drug discovery JV, Bexel Pharmaceuticals Inc (Bexel) has completed further proof-of-concept human clinical trials in various dosage regimens on its unique anti-diabetes BLX-1002 molecule. The studies pointed to the drug's unique efficacy in terms of not only glucose reduction but also lipid lowering and hypertension control. BLX-1002 has no PPAR affinity and does not have the adverse effect of weight gain or liver toxicity associated with certain recent anti-diabetes medications. The safety and tolerability of the drug in human volunteers has already been demonstrated in the earlier Phase I trials. All these trials have been conducted by a CRO in Europe based on approvals by the Independent Ethics Committee. Bexel is in structured discussions with various multinational corporations for potential out-licensing of the molecule. In parallel, Orchid and Bexel are working on developing a pipeline of compounds around BLX-1002 to enhance its positioning. BLX-1002 has already been covered by a patent issued by the US PTO admitting all the claims. Further patenting of the newer analogues has also been carried out.

Besides diabetes, Bexel has been working on leads in other metabolic diseases while Orchid has been working on in-house programmes of inflammation, oncology and infectious diseases.

Given the potential of drug discovery and development and the benefits from an integration of Orchid and Bexel competencies, Orchid has inked in the first quarter of the current fiscal an agreement with Bexel to increase Orchid's stake in the JV upto 75%, based on a mix of transfer of Orchid's IPR, contribution of cash and services. This would support a more robust pipeline of drug discovery, besides accelerating movement of select leads into clinical programmes, leveraging Bexel's front-end capabilities in clinical development.

The combined pipeline has a diversity of potential leads in the Inflammation area targeted at chronic and acute inflammatory diseases. One programme aims to develop an orally active small molecule which can inhibit TNFα. Such a development would be beneficial as current treatment comprises only injectable biopharmaceutical medications. Other parallel programmes have been taken up working on IL cytokine inhibition which could mediate relief from a number of inflammation diseases. Five leads are undergoing pre-clinical evaluation in this class of therapies.

Work in the area of obesity is focused on developing a novel orally active small molecule which could reduce adiposity and also inhibit enzymes in the body which could be involved in diet induced obesity.

In the area of anti-cancer therapies, certain novel mechanisms of actions are being explored. Pre-clinical evaluation, both on cancer cell lines and nude mice models, is being carried out to identify superior leads.

Given the focus on anti-infectives, Orchid has been working on novel as well as improved compounds in certain classes of antibiotics, including oxazolidinones. The goal is to develop molecules which offer better therapeutic regimen with lower toxicity compared to existing molecules.

Intellectual Property

Orchid has been a leading generator of intellectual property in the Indian pharmaceutical industry. Over the last three years, Orchid accelerated development of intellectual property across the five areas of process research, pharma research, new drug discovery, novel drug delivery systems and biotechnology.

As of June 2005, Orchid has filed 255 patent applications in the US, PCT, EP, India and other patent offices. Of these 174 have been published and 16 granted. Over 30 percent of the patents filed are in the fields of NCEs and NDDS indicating the level of innovation. During the fiscal under review, Orchid filed 85 patent applications. Six patents were received during the year from the US PTO as part of the 16 cumulative patents received so far.

ORCHID'S CUMULATIVE PATENT FILING COUNT IS 255*

Area	US	PCT	EP	India	Others	Total	Published	Granted
Process	31	19	3	96	36	185	118	15
NCEs	5	5	2	22	6	40	39	0
Formulations	4	6	0	17	0	27	17	1
Biotech	0	1	0	2	0	3	0	0
Total	40	31	5	137	42	255	174	16

*As of June 2005

Growth through transformation

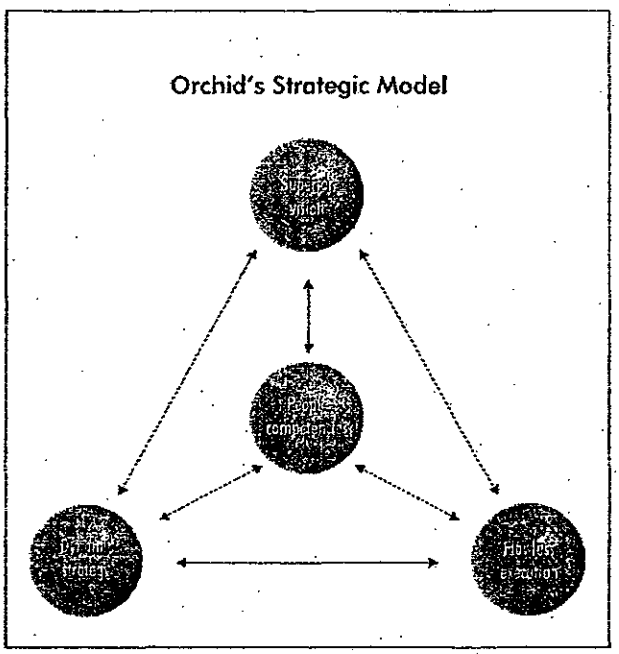
At Orchid, growth has been truly transformational, driven by fundamental enhancements in the composition of business, portfolio of products, versatility of manufacture and competencies of the organization. This remarkable transformation from a predominantly cephalosporin bulk drug and emerging market orientation to a multi-therapeutic composite pharmaceutical play with well-rounded capabilities in bulk drugs, formulations and drug discovery with a regulated market focus has been a challenging and exciting people effort, with the entire organization aligned in terms of superior vision, dynamic strategy and flawless execution.

The international pharmaceutical market valued at USD 500 billion, represents an exciting and challenging business opportunity for the Indian pharmaceutical industry. Yet, it is a market which is highly competed in terms of quality, innovation and compliance, cost efficiency and timeliness.

By setting for itself a superior vision that integrates challenging metrics on these dimensions, Orchid has aimed to achieve a notable niche in the global pharma space. To fulfill the vision, Orchid has chosen to adopt a strategic model that has the necessary reflex and responsiveness to meet the environmental, regulatory and competitive changes which are inevitable in a dynamic and growing global industry such as pharma. All this is backed by an execution paradigm that manages multiple projects to exacting timelines and integrates them into a seamless value chain focused on enduring customer relationships.

Orchid's vision for the future is as ambitious and aspirational as the transformation that has been achieved so far. Orchid is now firmly focused on becoming a truly global multi-therapeutic generics player and drug discovery major, in the process scaling a turnover of USD 1 billion by the turn of the decade. A diversified product portfolio, increased penetration in the regulated markets of US,

Orchid Chemicals & Pharmaceuticals Ltd.

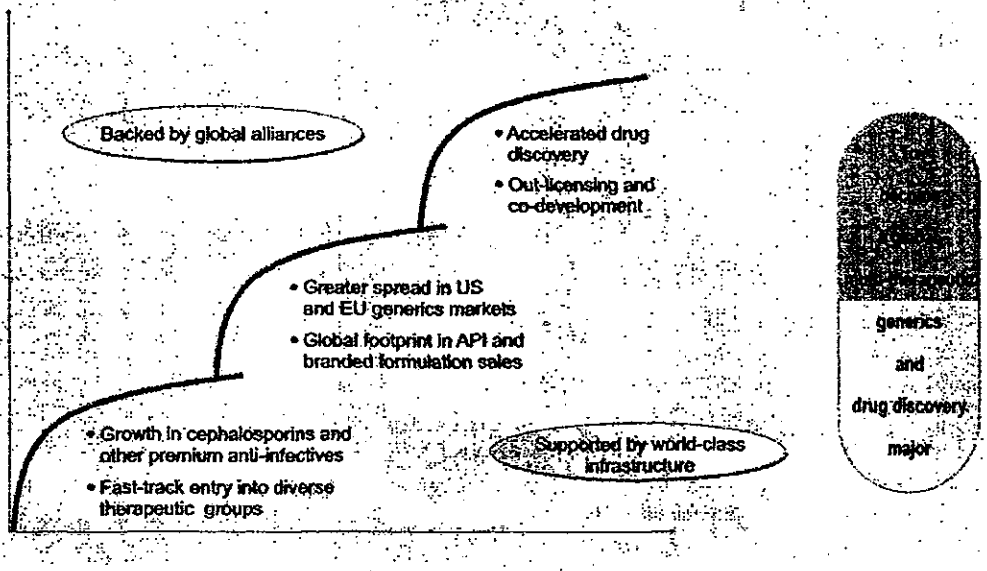


Europe and Japan and accelerated drug discovery would constitute the next canvas of strategic horizons for Orchid. An unrelenting emphasis on effective execution and an unwavering commitment to reducing the "time to market" would drive the differentiated performance at Orchid.

In order to meet the aspiration, Orchid's organization will continue to be strengthened in all critical areas relating to regulatory, intellectual property, research, manufacturing and marketing domains. Innovative paradigms in technology development, scale-up, outsourcing, manufacturing and supply chain management will be deployed to develop a high performance value chain across the organization.

As Orchid continues to explore new horizons of performance based on its model of strategic transformation, a competency based organization would be the key driver of performance. Initiatives are being taken on a continual basis to attract, develop and retain talent at all levels to build a value-driven and performance oriented organization that can set for itself and achieve superior levels of performance.

A robust business canvas with potential for quantum jumps in performance



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Orchid Chemicals & Pharmaceuticals Ltd.

BOARD OF DIRECTORS

CHAIRMAN	Shri R Narayanan
MANAGING DIRECTOR	Shri K Raghavendra Rao
DEPUTY MANAGING DIRECTOR	Dr C Bhaktavatsala Rao

DIRECTORS

Dr M R Girinath	Dr I Seetharam Naidu
Shri Deepak Vaidya	Shri Subramanian Andi (IDBI Nominee)
Dr Anzaghi Piergiorgio	Shri Anil Thadani
Dr Bishwajit Nag	Dr Francis Pinto

MANAGEMENT TEAM

Shri R S Prasad	Executive Director & Chief Executive Officer (Formulations)
Shri A R Chandrasekharan	President – Corporate Finance
Dr Gautam Kumar Das	President – Technical (Bulk Drugs)
Dr G Om Reddy	President & Chief Scientific Officer
Dr Sumant Baukhandi	President – Regulatory Affairs & Quality (Bulk Drugs)
Shri B Vasudevan	President – API (Manufacturing)
Shri Ashutosh Ojha	Country Head (Domestic Formulations)
Shri D S Bhaskara Raju	Vice President – Business Planning & Development
Shri C R Dwarakanath	Vice President – Works (Alathur)
Ms Edna Braganza	Vice President – Commercial
Shri Kalidindi V Raju	Vice President – Works (Irungattukottai)
Shri Makarand M Deshpande	Vice President – International Marketing
Shri S Mani	Vice President – Projects & Engineering
Shri Pravir Choubey	Vice President – Regulatory & Compliance (Formulations)
Shri M S Rangesh	Vice President – Human Resources
Dr Sriram Rajagopal	Vice President – Biology
Shri L Chandrasekar	Sr General Manager – Internal Audit & Secretary
Shri A Suresh Babu	Sr General Manager – Corporate Affairs
Shri Umesh D Kapre	Sr General Manager – Works (Aurangabad)

REGISTERED OFFICE
'Orchid Towers'
313, Valluvar Kottam High Road
Nungambakkam
Chennai, Pin 600 034
Tamil Nadu, India

R&D CENTRES
Plot No.476/14
Old Mahabalipuram Road
Sholinganallur, Chennai
Pin 600 119, Tamil Nadu, India

Plot Nos. B21 – B23 & B31 – B33
SIPCOT Industrial Park, Irungattukottai
Sriperumbudur (Tk.), Pin 602 105.
Kancheepuram District, Tamil Nadu, India

BANKERS
Allahabad Bank
Bank of Baroda
Bank of India
Canara Bank
ICICI Bank Ltd
IDBI Limited
Indian Bank
Punjab National Bank
State Bank of India
Union Bank of India

API FACILITIES
ALATHUR WORKS
Plot Nos. 85-87, 98-100, 126-131
138-151 and 159-164
SIDCO Industrial Estate
Alathur, Kancheepuram District
Pin 603 110, Tamil Nadu, India

AURANGABAD WORKS
L-8 & L-9 MIDC Industrial Area
Waluj, Aurangabad District, Pin 431 136
Maharashtra, India

FORMULATIONS FACILITIES
A10/A11, SIDCO Industrial Estate
Alathur, Kancheepuram District
Pin 603 110, Tamil Nadu, India

B-77, SIDCO Pharmaceutical Complex
Alathur, Kancheepuram District
Pin 603 110, Tamil Nadu, India

Plot Nos. B3 – B6 & B11 – B14
SIPCOT Industrial Park, Irungattukottai
Sriperumbudur (Tk.), Pin 602 105,
Kancheepuram District, Tamil Nadu, India

AUDITORS
STATUTORY AUDITORS
SNB Associates
Chartered Accountants
No. 12, 3rd Floor, Gemini Parsn Complex
121, Anna Salai, Chennai, Pin 600 006
Tamil Nadu, India

US GAAP AUDITORS
Deloitte Haskins & Sells
Chartered Accountants
476, Temple Towers, 2nd Floor, Nandanam
Chennai, Pin 600 035
Tamil Nadu, India

COST AUDITORS
Shri V Kalyanaraman
Cost Accountant
No. 4 (Old No.12), Second Street
North Gopalapuram, Chennai, Pin 600 086
Tamil Nadu, India

DIRECTORS' REPORT

Your Directors have pleasure in presenting the Thirteenth Annual Report of your Company along with the audited Statement of Accounts for the financial year ended March 31, 2005. The Report also includes the Management Discussion and Analysis Report in accordance with the Guidelines on Corporate Governance and Consolidated Financial Statements.

The highlights of the financial results for the year 2004 - 2005 are as below:

Rs lakhs

Particulars	Year Ended 31.03.2005	Year Ended 31.03.2004
Sales & Operating Income	68929.44	71340.97
Other Income	82.23	123.12
Total Expenditure	52700.68	56414.99
Gross profit	16310.99	15049.10
Interest & Finance Charges	7231.00	6067.08
Gross Profit after Interest but before Depreciation and Taxation	9079.99	8982.02
Depreciation	6189.19	5684.23
Profit Before Tax	2890.80	3297.79
Provision for Taxation		
– Current Tax	194.60	195.00
– Deferred Tax	(404.93)	–
Profit after Tax	3101.13	3102.79
Add: Surplus brought forward	2203.99	1562.44
Surplus available	5305.12	4665.23
Appropriations:		
– Transfer to General Reserve	1000.00	1000.00
– Dividend	1365.28	1295.28
– Tax on distributed profits	191.48	165.96
Balance carried to Balance Sheet	2748.36	2203.99

Performance

During the year under review your Company achieved a turnover and operating income of Rs 689.29 crore compared to Rs 713.41 crore in the previous fiscal year 2003-04. Gross profit before interest, depreciation and taxes in 2004-05 was higher at Rs 163.11 crore compared to Rs 150.49 crore in the previous fiscal.

After providing for interest of Rs 72.31 crore (Rs 60.67 crore previous fiscal) and depreciation of Rs 61.89 crore (Rs 56.84 crore previous fiscal), the profit before tax of the Company was Rs 28.91 crore as against the previous year's profit before tax of Rs 32.98 crore. Net profit after tax stood at Rs 31.01 crore, at the same level as in the previous fiscal despite the marginal decline in the sales and operating income.

Active Pharmaceutical Ingredients (API) Business

During the fiscal year under review, Orchid continued to maintain its strong position in the global cephalosporin markets. The sale of all bulk actives was Rs 566 crore compared to Rs 595 crore in 2003-04. Sale of oral bulk actives accounted for Rs 428 crore (Rs 385 crore previous fiscal) and sterile bulk actives brought in revenues of Rs 138 crore (Rs 210 crore previous fiscal). The Company sold 950 MT of bulk actives and intermediates during the year under review compared to 1038 MT previous fiscal. Despite the price pressures and competitive markets, focus on value-added product mix supported revenue and profit targets.

During the last quarter of 2004-05, your Company completed a new manufacturing facility for non-penicillin, non-cephalosporin bulk drugs in Aurangabad. This facility which is undergoing validations will be a key driver of the Company's

strategy to enter into diverse therapeutic groups, aimed at regulated markets.

Formulations Business

The turnover of the formulations business was Rs 81 crore during the fiscal, compared to Rs 103 crore last fiscal. While the international business grew by 11%, the domestic business had a decline, due to the considerable de-stocking resorted to by the trade channels in the wake of proposed introduction of Value Added Tax (VAT). This has affected all the pharmaceutical companies including Orchid during Q4 of the fiscal under review.

Your Company also carried out various organizational and systemic improvements during the year in the domestic business which are expected to result in higher performance from Q2 of 2005-06 onwards, although in the near term the fall-out of VAT introduction may continue to keep the demand depressed while application of excise duty based on Maximum Retail Price (MRP) may affect outsourcing economics and affect margins of such products.

During Q4 of 2004-2005, more international registrations have been made for enhancing export business. Your Company has been penetrating new export markets for formulations. Your Company has registered several cephalosporin and non-cephalosporin products in CIS, Africa and South East Asian countries during the year 2004-05. The registration process is in progress in Europe and Brazil also. Your Company plans to focus on a few less regulated markets also, with relevant product lines.

Your Company's state-of-the-art formulations facility located at Irungattukottai, near Chennai was inspected by the US FDA in February – March 2005. The US FDA inspection covered the full spectrum of oral and sterile cephalosporin formulation manufacturing blocks with a review of 9 Abbreviated New Drug Applications (ANDAs) spanning the 4 dosage forms of sterile injectables, tablets, capsules and dry powder syrups. The successful inspection, without any negative observation, recognises the world-class infrastructure and high-technology competency base that has been established at Orchid in the finished dosage forms arena.

Additional facilities for high-end betalactam formulations and non-penicillin, non-cephalosporin formulations will be completed and utilized for ANDA filings from the middle of this fiscal 2005-06. The formulations R&D activity is also being expanded and relocated contiguous to the generics complex for better connectivity with operations.

Dividend

Your Directors recommend a dividend payment of 40% (Rs 4 per equity share of Rs 10 each) for the year ended 31st March 2005 subject to the approval of shareholders in the ensuing Annual General Meeting. Under the Income Tax Act, 1961, the receipt of dividend is tax-free in the hands of the shareholders.

Regulatory Approvals

Your Company increased the pace of regulatory filings in the cephalosporin space. Your Company has so far filed 16 US DMFs and 18 ANDAs to support its US generics thrust. The Company's Irungattukottai formulations complex, near Chennai has been in the forefront of Orchid's foray into regulated markets with an aggressive pace of ANDA filings. The 18 ANDAs have been submitted with the US FDA within a short span of one year. More US regulatory filings will be made this fiscal covering the cephalosporin and non-cephalosporin product range.

Subsequent to the US FDA inspection of the Irungattukottai (IKKT) plant, Orchid received on April 21, 2005 the formal US FDA approval for Cefazolin generic injectable product. This is a significant milestone for the US generics business as it paves way for commercial launch into the US market. It is expected that further approvals for the ANDAs reviewed and also those in the queue would be received progressively.

Your Company has also been awarded Certificates of Suitability (CoS) from the European Directorate for the Quality of Medicines (EDQM) for 9 of its products.

Marketing Alliances

During the year under review (2004-05), impressive progress has been made in the execution of the generics strategy in terms of establishing infrastructure, building organizational capabilities, leading to regulatory approvals and extending marketing alliances. The state-of-the-art formulations facility at Irungattukottai (IKKT), near Chennai has emerged as a major driver of the regulated market business for the future.

The entry and growth in the US generics market will be based on 15 key antibiotic products, including certain premium, high-margin products that are scheduled to go off patent progressively between 2005 and 2008. Orchid has exclusive marketing arrangements with Apotex and Par Pharmaceuticals, both international generic corporations of repute, to market these sterile and oral antibiotic formulations respectively in the US. The marketing alliance with Apotex has also been extended to the Canadian market for the sterile antibiotics. Your Company has an agreement with MX Animal Health, Inc. (formerly Phoenix Scientific Inc.) to distribute a key veterinary cephalosporin injectable which is yet to be genericised, in US, Canada and Mexico.

Your Company has recently entered into further exclusive distribution agreements for the non-penicillin, non-cephalosporin dosage forms for which investments are being made. The agreement with Alpharma is for marketing 10 of

Orchid's non-antibiotic generic formulations in US and Europe, while the agreement with STADA Pharmaceuticals, Inc., the US subsidiary of STADA Arzneimittel AG, is for distribution of 6 prescription generic drug products in the US market. The third agreement is with Par Pharmaceutical for 4 generic products to be marketed in the US. Through these three agreements, Orchid will develop and exclusively manufacture 20 non-cephalosporin formulations for exclusive distribution and marketing by the respective partners. All the agreements provide for beneficial commercial terms including upfront development funding for Orchid. The ANDAs will be owned and maintained by Orchid.

Research & Development

During the year, Orchid's R&D made significant progress covering new drug discovery, process research and biotechnology, besides pharma research which has been driving the formulations and regulated market effort.

Several cephalosporin API products have been developed for commercial manufacture based on non-infringing processes specifically for regulated markets. Pilot plant trials have been completed for more cephalosporins while additional cephalosporin molecules are under active development. These initiatives would provide a product pipeline in the mature cephalosporin space as well, for regulated as well as less regulated markets.

Within the anti-infectives, Meropenem, the first product developed by R&D in this category, was successfully manufactured by the Company, securing the distinction of being the first to manufacture this drug in India. To enable the Company achieve a futuristic area of core competence, R&D has drawn up plans for development of additional challenging molecules and intermediates in the anti-infective class.

During the first quarter of the current fiscal Orchid has entered into an agreement with Bexel to increase Orchid's stake in the JV upto 74%, based on the contributions of a mix of Orchid's select IPR, cash and services. Your Company believes that this move would help generate greater value from the drug discovery pipeline in the overall.

In order to increase the product breadth and business base, new initiatives have been taken up by Orchid to add products of diverse therapeutic groups. This program will add several non-antibiotic molecules to the range of anti-infective products of cephalosporins, betalactums and penems. R&D is actively engaged in the development of such products.

Your Company's R&D strategy envisions a major role for the drug discovery joint venture in the US, Bexel Pharmaceuticals Inc. Orchid's discovery chemistry and biology have been of continuous support to Bexel. The lead anti-diabetes molecule BLX-1002 has successfully completed human clinical trials covering safety and tolerability as well as proof-of-efficacy. Discussions are on with select MNCs with regard to outlicensing of the molecule. Orchid and Bexel have also been working on developing and evaluating several other leads in the chosen therapeutic areas.

In order to provide additional focus and impetus to the Company's efforts, especially in the area of drug discovery and development and to leverage on the incentives for exclusive R&D entities / operations, your Company has established a Company by name Orchid Research Laboratories Limited. Your Board will deliberate further options for this entity, including constitution as a wholly owned subsidiary and channeling of research programmes.

Intellectual Property

During the year, Orchid continued to accelerate the IPR work on a number of products. Six patents (all from US-PTO) were received during the year (5 in API and 1 in formulation) taking the total patent count to 14. The total number of patent applications filed and maintained by Orchid in various international patent offices during the financial year 2004-05 was 85, taking the cumulative count to 234. The total number of patents and patent applications published during the year was 68.

Long Term Resources

In order to fund the long-term plans, the Board of your Company earlier decided that resources could be raised through issue of appropriate securities including the issue of Foreign Currency Convertible Bonds (FCCBs) in the international markets and had obtained the approval of the shareholders for the said issue. The issue was deferred due to changing market conditions.

Your Board is also considering other options for securing of long-term funds by way of issue of shares on overseas retail or private placement basis. The Board would review and present its recommendations for shareholders' approval.

Issue of Warrants

Your Company had allotted 20,00,000 (twenty lakh only) Warrants to the Promoter / Promoter Group(s) during April 2004, pursuant to the approval granted by the members of the Company at the Extraordinary General Meeting held on April 10, 2004. These Warrants were eligible for conversion at the option of the Warrant holders, into equity shares of the Company at a price of Rs 212.18 per share within a period of 18 months of the date of allotment.

Pursuant to the exercise of the options by the warrant holders, the Allotment Committee of the Board of Directors of your

Company on March 1, 2005, have allotted 17,50,000 (seventeen lakh fifty thousand only) equity shares of Rs 10/- each arising out of the conversion of 17,50,000 warrants (out of the total allotted warrants of 20,00,000) to Promoters (Mrs R Vijayalakshmi – 7,50,000 shares and M/s Orchid Healthcare Private Limited – 10,00,000 shares).

Listing of Equity Shares

Your Company's equity shares are presently listed on the National Stock Exchange of India Limited (NSE), the Stock Exchange, Mumbai (BSE) and the Madras Stock Exchange Limited (MSE). The Company has applied for listing of the newly issued 17,50,000 equity shares to the Stock Exchanges where the Company's shares are listed. In-principle approval from NSE and BSE has been received for listing and the final approval will be obtained subject to complying with certain requirements of the Exchanges. The Company is in the process of complying with these requirements.

Overseas Joint Ventures

NCPC Orchid Pharmaceuticals Company Limited – China: Your Company's joint venture in China, NCPC Orchid Pharmaceuticals has been progressing well. Orchid's technical team has successfully demonstrated processes for certain cephalosporin products at the NCPC-Orchid plant in China. Your Company has since completed the technology transfer successfully for 2 more products and the commercial manufacture of such products has been taken up by the joint venture. The initial response from the market has been good and the JV Company's product range has the largest share in the Chinese market. The JV is planning to enhance the market share further in the current year. During the year under review, which was the first full year of operations, NCPC-Orchid recorded a turnover of US$ 20 million, which is considered creditable.

Bexel Pharmaceuticals Inc. – USA: The US discovery joint venture which has been working on a novel anti-diabetic molecule (BLX-1002), has successfully completed escalating dose Phase 1(a) and multiple dose Phase 1(b) safety and tolerability studies and Phase 1(c) and 1(d) limited proof-of-concept clinical trials in Europe. The studies have shown promising results. The proof-of-concept studies on diabetic volunteers showed the molecule's efficacy in not only reducing glucose but also controlling lipid profile and blood pressure. The molecule does not induce weight gain unlike other known anti-diabetic compounds. The US PTO has granted a patent covering among others the molecule and admitting all claims. Discussions have since been initiated for out-licensing the molecule with select MNCs, who have shown interest in the molecule. The joint venture is also conducting pre-clinical studies on its anti-obesity and anti-inflammatory molecules.

Biotechnological Chemical Development Limited – United Kingdom: The joint venture was set up as a limited time horizon project to develop and assimilate select peptide technologies. As the technological platform has been developed and demonstrated, your Company proposes to transfer the equipment, IPRs and other assets of the JV to India. Your Company feels that it would be beneficial to carry on further development work in India at its facilites.

Subsidiaries

Orchid Europe Limited – United Kingdom: Your Company's wholly owned subsidiary Orchid Nutricare limited has been renamed as Orchid Europe Limited considering the future course of business activities. The future business of Orchid Europe would be in terms of pharmaceutical generics and your Company proposes to utilise this entity for generics registrations to start with.

Ogna Farma – Brazil: Brazil is a large and fast growing market for cephalosporins. In order to tap this opportunity, your Company has established a subsidiary in Brazil to cater to the product registration and marketing requirements. Applications are being submitted by your Company for inspection of the injectable formulations facilities at Irungattukottai, by the Brazilian regulatory authorities.

Gene Arrays Inc. – USA: Orchid entered into a joint venture arrangement in USA to establish Gene Arrays Inc. as a company specializing in products and services based on microarrays. The company is headquartered in Maryland, USA. As the skill-sets and market opportunities for this sunrise kind of activity are concentrated in the US, the JV has been set up as an exploratory venture to familiarise your Company with the technologies and developments.

Orchid Pharmaceuticals Inc. – USA: The US coordination work including acting as agent for filing of regulatory submissions with the US FDA was being carried out through a branch office in New Jersey, USA hitherto. In order to cater to the more demanding requirements of the US market, the Board felt that it would be more appropriate to have a separate entity formed in the US. Accordingly, your Company promoted Orchid Pharmaceuticals Inc. in Delaware state of USA as a 100% subsidiary company during the year under review.

Your Company has received an approval under Section 212 (8) of the Companies Act, 1956 from the Department of Company Affairs, Ministry of Finance vide letter no.47/104/2005-CL-III dated 6th April 2005 exempting the Company from the provisions contained in sub-section (1) of Section 212 of

the Companies Act, 1956. The statement as required under the said approval is given as part of the consolidated accounts in the report. Further, the consolidated financial statements of Orchid including its subsidiaries duly audited are presented in this Report. The annual accounts of the subsidiary companies and the related detailed information shall be made available to the members seeking such information at any point of time. Further, the annual accounts of the subsidiary companies are kept at the Registered Office of your Company and also at the respective registered offices of the subsidiaries for inspection.

Environment, Safety and Health

Your Company continued to conform to high standards of environmental friendliness. Your Company's Aurangabad Unit obtained prestigious ISO 14001 and OHSAS 18001 certifications for environmental management and occupational health and safety management systems.

Safety was accorded a high priority in all activities and at all locations throughout the year. To create safety awareness, training programmes were regularly conducted for the employees and contract workers with the help of faculty and experts in the field. In-built safety systems have been incorporated in all the projects.

With the evolution into a multi-locational organisation, your Company has taken up additional initiatives to further strengthen and harmonise safety, health and environment management systems at all locations within a corporate policy framework. Accordingly, the Corporate Safety Health & Environment (SH&E) function has been formed in April 2005. This would further reinforce and sustain your Company's logical position as a benchmark in the industry in matters relating to safety, health and environment.

Tsunami Relief Efforts

Your Company has been actively involved in providing relief to those affected by the Tsunami in the coastal areas of Tamil Nadu and Pondicherry. Immediately after the damage, Orchid extended help to the local community which included provision of transport, food and essential medical attention till they were accommodated in the rehabilitation camps set up by the Government. Your Company contributed significantly to the relief operations by way of physical help as well as donating medicines. All employees of your Company have contributed a day's salary, which was matched by an equal contribution by the Company. The amount was handed over to the Hon'ble Chief Minister of Tamil Nadu.

Fixed Deposit

The Company has not accepted any fixed deposits and as such, no amount of principal or interest was outstanding as of the Balance Sheet date.

Directors' Responsibility Statement

In accordance with the provisions of Section 217 (2AA) of the Companies Act, 1956, your Directors confirm:

- That in the preparation of the annual accounts for the year 2004-05, the applicable accounting standards have been followed by your Company along with proper explanation relating to material departures, if any.
- That the Directors have selected such accounting policies and applied them consistently and made judgments and estimates that are 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 (31st March 2005) and of the profit or loss of the Company for that period (2004-05).
- 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.
- That the Directors have prepared the annual accounts 2004-05 on a going concern basis.

Conservation of Energy

Your Company has always been striving hard in the field of energy conservation. Several measures to conserve energy and to reduce the costs associated with it have been taken. Particulars in respect of conservation of energy as required under Section 217 (1)(e) of the Companies Act, 1956, are given in Annexure I to this report.

Foreign Collaboration

The particulars in respect of R&D / Technology absorption as required under Section 217 (1)(e) of the Companies Act, 1956, are given in Annexure II to this Report.

Foreign Exchange Earnings and Outgo

The particulars in respect of Foreign Exchange Earnings and Outgo as required under Section 217 (1)(e) of the Companies Act, 1956, are given in Annexure III to this Report.

Particulars of Employees

Information as per Section 217(2A) of the Companies Act, 1956 read with Companies (Particulars of Employees) Rules, 1975 forms part of this Report and is given in Annexure IV to this Report.

Orchid Chemicals & Pharmaceuticals Ltd.

Corporate Governance

Your Company has been according high importance for ensuring corporate governance and has also been following the code of corporate governance issued by the Stock Exchanges for listed companies. For the year 2004-05, the compliance report is provided in the Corporate Governance section in this report. The Auditor's Certificate on compliance with the mandatory requirements of Corporate Governance is given in Annexure V to this Report.

Employees Stock Option Plan

The Company has granted 9,07,925 options upto March 31, 2005 to the employees in two tranches, each option being convertible into one equity share of nominal value of Rs 10 each, under the ORCHID–ESOP 99 scheme. The Allotment Committee of the Board at its meeting held on April 27, 2005 allotted 11,800 shares to employees upon exercise of the Stock Options. Further 2,92,075 options have been granted to employees and independent directors of the Company by the Compensation Committee of the Board at its meeting held on April 27, 2005. Each such option is convertible into one equity share at a price of Rs 300.65 per share. The details of the options granted to employees and the status of such options as on March 31, 2005 are given in Annexure VI to this report.

Directors

In accordance with the provisions of the Companies Act, 1956, and the Articles of Association of the Company, Shri Anzaghi Piergiogio, Dr M R Girinath and Shri Deepak Vaidya retire by rotation at the forthcoming Annual General Meeting and being eligible offer themselves for re-appointment.

Auditors

The existing Statutory Auditors, M/s SNB Associates, Chartered Accountants retire at the forthcoming Annual General Meeting, and being eligible, offer themselves for re-appointment.

Cost Audit

The Central Government has prescribed that an audit of the cost accounts maintained by the Company in respect of bulk drugs and formulations be conducted under Section 233B of the Companies Act, 1956. Consequently, your Company has appointed Shri V Kalyanaraman, B.Sc., FICWA, as Cost Auditor for the year 2004-2005, with the consent of the Central Government, for the audit of cost accounts maintained by the Company in respect of both bulk drugs and formulations.

Acknowledgements

Your Directors are thankful to Bank of India, IDBI Limited, State Bank of India, ICICI Bank Limited, Indian Bank, Union Bank of India, Allahabad Bank, Canara Bank, Punjab National Bank, Bank of Baroda and other public sector and private sector banks and institutions for meeting long term and working capital needs of the Company's expanding operations.

The Directors are grateful to the Central and State Governments and the Central DCGI and State FDAs for their continued support to the Company's expansion plans. Your Board places on record its appreciation of the support provided by the customers, suppliers and equipment vendors to the Company. Your Directors are also thankful to the vendors, distributors and agents for their continued support.

Your Directors are thankful to the esteemed shareholders for their support and encouragement, which has enabled the Company to venture into various projects successfully. The Directors acknowledge the commitment and contribution of all employees to the growth of the Company.

For and on behalf of the Board

R NARAYANAN
Chairman

Place: Chennai
Date : April 27, 2005

Addendum to the Directors' Report

The Board at its meeting held on June 15, 2005 considered certain issues, subject to the approval of the shareholders. The said resolutions are placed before the members for approval in the ensuing Annual General meeting and the notice for the same is enclosed with the Report.

Raising of Long Term Resources through GDRs and Warrants

Your Company has set up world-class infrastructure in API, formulations and drug discovery segments of the business to emerge as a composite pharmaceutical major focused on regulated markets such as the United States and Europe. This would help your Company take its cephalosporin products to the regulated markets from the current fiscal, and also launch the first wave of non-cephalosporin products from fiscal 2008 for which the investments have been made in R&D, API pilot plant and formulation pilot plant, infrastructure for product developments, regulatory filings and initial commercial manufacture.

Your Company's investment programmes were funded by the proceeds of the earlier equity placements, cash accruals from ongoing operations and borrowings.

However, further broadening of development and regulatory work for the larger list of products from the multiple therapeutic groups as well as an acceleration of drug discovery would propel your Company to an even higher trajectory of growth from fiscal 2008. Your Company has identified several product opportunities in multiple therapeutic segments (other than anti-infectives) as well as certain futuristic niche anti-infectives to drive such incremental growth. Simultaneously, there is also a need to de-leverage the Company and reduce the interest costs.

Your Company now needs to implement the supplemental business model with a larger product spread to achieve further growth momentum from 2007-08 and beyond, with a low-cost, de-leveraging financial plan.

In order to meet further financial outlay on such multi-therapeutic expansion and also to accelerate drug discovery and to reduce the interest burden, your Company's Board at its meting held on June 15, 2005, have proposed to raise long term resources through Global Depository Receipts (GDRs) in the international capital markets to the tune of US$ 100 million, with an additional 15% Green Shoe Option and issue of 25 lakh Warrants, convertible into Equity Shares to the Promoter(s) / Promoter Group(s) in accordance with the Guidelines of Securities & Exchange Board of India for Preferential Issue. It is proposed to list the GDRs on the Luxembourg Stock Exchange.

Employee Stock Options

Orchid has been offering stock options to its employees to retain talent and promote participation and ownership in the Company. Given the competitive environment and long term growth plans it is essential that the Company should take further initiatives in this direction.

Your Company is seeking the approval of the members for grant of 10 lakh options to employees in accordance with SEBI (ESOS & ESPS) Guidelines, 1999.

Directors

Pursuant to the subscription agreement entered with M/s. Gazal Industrial Holdings Limited and M/s. Right On Time Limited, the investors have a right to appoint three directors on the Board of your Company. Shri Sanjay K Sehgal, Symphony Capital Partners (Asia) Pte. Ltd. (formerly "Schroder Capital Partners Limited") has resigned from the Board of your Company. The Board places on record its appreciation for the valuable contributions made by Shri Sanjay K Sehgal as Director. Your Company's Board at its meeting held on June 15, 2005, have appointed Shri Anil Thadani to fill up the casual vacancy caused by the resignation of Shri Sanjay K Sehgal.

Pursuant to the terms of the loan agreement entered into with Industrial Development Bank of India, Shri Subramanian Andi has been appointed as its nominee on the Board effective May 19, 2005 in place of Shri Mahendra Kumar Chouhan. Your Directors place on record their appreciation of the valuable services rendered by Shri Mahendra Kumar Chouhan during his tenure as Director.

Listing of Equity Shares

In the Directors report, your Directors stated that your Company had applied for listing of the newly issued 17,50,000 equity shares to the Stock Exchanges where the Company's shares are listed namely National Stock Exchange of India Limited (NSE), The Stock Exchange, Mumbai (BSE) and Madras Stock Exchange Limited (MSE).

Pursuant to the application made by your Company to the Stock Exchanges, your Company has received final approval for the listing of the equity shares from NSE, BSE and MSE.

Orchid's Equity Shares in Futures & Options Segment (F&O)

The National Stock Exchange of India Limited (NSE) vide its Circular No: NSE/F&O/100/2005 dated April 15, 2005 notified that the securities of Orchid would be made available for trading in F&O segment effective May 12, 2005. Accordingly, your Company's equity shares have been made tradable in the Futures & Options segment.

For and on behalf of the Board

R NARAYANAN
Chairman

Place: Chennai
Date : June 15, 2005

Statement pursuant to Section 212 of the Companies Act, 1956, relating to subsidiary companies.

Rs lakhs

	Name of the Subsidiary Company	Orchid Europe Limited (formerly Orchid Nutricare Limited), United Kingdom	Ogna Forma Distribuicao Importacao, Exportacae e Assessoria Ltda, Brazil	Gene Arrays Inc., United States of America	Orchid Pharmaceuticals Inc., United States of America
2	The financial year of the subsidiary Company ended on	31-Mar-05	31-Dec-04	31-Dec-04	*
3	Holding Company's interest	100% in equity shares	97.71% in common stock	66.67% convertible preferred stock with equal voting rights as common stock	100% in common stock
4	Shares held by the holding Company in the subsidiary	10,000 equity shares of 1 GBP each	**	200000 equity shares of 0.001 US$ each	100 equity shares of 1 US$ each
5	The net aggregate of profit/(loss) for the current period of the Subsidiary so far as it concerns the members of the holding Company				
	a) Dealt with or provided for in the accounts of the holding Company	(1.09)	(25.18)	(91.85)	NA
	b) Not dealt with or provided for in the accounts of the holding Company.	Nil	Nil	Nil	NA
6	The net aggregate of profit/(loss) for previous financial years of the Subsidiary so far as it concerns the members of the holding Company				
	a) Dealt with or provided for in the accounts of the holding Company	(2.60)	(21.50)	Nil	NA
	b) Not dealt with or provided for in the accounts of the holding Company.	Nil	Nil	Nil	NA

* Incorporated during October 2004 and the first accounts would be prepared and audited for the period ended December 31, 2005

** As per the Brazilian law, issue of share certificate towards equity contribution is not in practice. Hence, the holding company's interest can be considered as the holding in subsidiary.

On behalf of the Board

R NARAYANAN
Chairman

K RAGHAVENDRA RAO
Managing Director

DR C BHAKTAVATSALA RAO
Deputy Managing Director

DR I SEETHARAM NAIDU
Director

A R CHANDRASEKHARAN
President – Corporate Finance

L CHANDRASEKAR
Sr. GM – Internal Audit & Secretary

Orchid Chemicals & Pharmaceuticals Ltd.

Place : Chennai
Date : April 27, 2005

OCP0000372

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ANNEXURE TO THE DIRECTORS' REPORT

INFORMATION UNDER SECTION 217(1)(e) OF THE COMPANIES ACT, 1956 READ WITH COMPANIES (DISCLOSURE OF PARTICULARS IN THE REPORT OF BOARD OF DIRECTORS) RULES, 1988 AND FORMING PART OF DIRECTORS' REPORT FOR THE YEAR ENDED 31ST MARCH, 2005.

ANNEXURE I – CONSERVATION OF ENERGY

a) Energy conservation measures taken

Following energy conservation measures were taken in the manufacturing plants.

- The introduction of additional control loops and separate brine return lines from load less condensers in Multi Purpose Solvent Recovery chiller circuit resulted in saving power.
- The entire plant was audited to reduce the nitrogen losses and as a result of certain improvements made in the existing system, nitrogen flow rate has been reduced.
- The efficiency of – 70 degree refrigeration system improved by a few modifications (three stage to two stage conversion, installation of on-line methanol circulation system etc).
- The cooling water systems used in the plants were modified to reduce power consumption.
- Heat load in the centralized air conditioning system was reduced in order to minimize usage of power.

b) Additional investments and proposals, if any, being implemented for reduction of consumption of energy

Some of the proposals that are considered / being implemented for saving energy consumption are :

- Using the heat energy from HT circuits of Captive Power Plants in a hot water fired VAS to produce 400 Tonnes of Refrigeration chilling effect.
- Replacement of VAS system with water-cooled vapour compression system.
- Heat recovery from the vapours from crystalizer plant to generate flash steam and thermo compressing it.
- Introduction of economisers in the downstream side of Waste Heat Recovery Boiler of Captive Power Plant-1 & Captive Power Plant-2

c) Impact of the measures at (a) and (b) above for reduction of energy consumption and consequent impact on the cost of production of goods

Due to the energy conservation measures adopted by the Company during the year under review, the Company could achieve saving of around 9300 units of electricity consumption per day, leading to a saving of around Rs.90 lakhs per annum.

Further the energy conservation measures proposed to be taken up by the Company as mentioned in (b) above is expected to bring a savings of about Rs 133 lakhs per annum.

d) Total Energy Consumption and energy consumption per unit of production

A POWER AND FUEL CONSUMPTION	Year ended March 31, 2005	Year ended March 31, 2004
1 Electricity		
a) Purchased:		
Units	6640944	5799920
Total amount (Rs lakhs)	232.68	222.84
Rate per unit (Rupees)	3.50	3.84
b) Own generation:		
i) Through Diesel generator:		
Units	1696866	3556935
Units per litre of diesel oil	3.55	3.38
Cost per unit (Rupees)	5.80	4.74

Orchid Chemicals & Pharmaceuticals Ltd.

	Year ended March 31, 2005	Year ended March 31, 2004
ii) Through Furnace Oil generator:		
Units	70164321	70645986
Units per litre of fuel oil	4.29	4.31
Cost per unit	2.64	2.27
2. Coal		
Quantity (tonnes)	Nil	Nil
Total Cost	Nil	Nil
Average rate	Nil	Nil
3. Furnace oil		
Quantity (K litres)	28656.75	28204.21
Total cost (Rs lakhs)	2681.33	2520.58
Average rate (Rs per KL)	9356.72	8936.90
4. Others/internal generation		
Details: Windmills		
Quantity (in units)	2498713	2209842
Rate per unit (Rs)	2.70	2.72
B CONSUMPTION PER UNIT OF PRODUCTION		
Products with details:		
Bulk Drugs & Intermediates		
Oral & Sterile (in MT)	754.90	741.00
Electricity (Rs lakhs per MT)	2.58	2.39
Furnace Oil (Rs lakhs per MT)	3.54	3.40
Coal	Nil	Nil
Others	Nil	Nil

ANNEXURE II – TECHNOLOGY ABSORPTION

I. RESEARCH AND DEVELOPMENT

1. Specific areas in which research and development activities have been carried out by the Company during the year.

The Research & Development activities of the Company are in terms of Non-infringing Process Research, New Drug Discovery, Analytical Research, Novel Drug Delivery Systems and Biotechnology.

A few cephalosporins for meeting the requirements of the joint venture in China were developed.

Your Company's R&D has developed Meropenem, a member of the carbapenem family and successfully manufactured the product in the plant.

Your Company's R&D has developed technology for a few non-penicillin and non-cephalosporin APIs, in line with the Company's plans to expand the product line and the business base by adding new molecules other than the ongoing cephalosporins and the penems.

New Drug Discovery has focussed on the design, synthesis and screening of several New Chemical Entities (NCEs) covering the anti-infective, anti-bacterial, anti-inflammatory and anti-cancer segments.

Several patents were filed in anti-infective, anti-inflammation, anti-diabetes and anti-cancer segments based on the novelty and activity of compounds developed.

New initiatives include establishment of cell culture and biochemistry facility to develop cell based and target based screens. Additional biological screening methods are being continually added. A new initiative on nano-technology was also taken up at the R&D centre to address the insoluble and very reactive NCEs.

New instruments were purchased to support bio-analytical applications of the NCEs being synthesized by New Drug Discovery division. This would enable your Company to accelerate pharmaco-kinetic and metabolism studies.

Your Company's Biotechnology division has demonstrated a fermentative mode of manufacture of a key intermediate by successfully transferring the modified expandase genes and in optimization and scale-up efforts of the same process. An application to protect the innovating enzyme mutants for the evolution of the technologies for the manufacture of two other critical intermediates would be filed shortly. Efforts are underway for early commercialization of these biotransformation technologies.

The Company's pharmaceutical research division focussed aggressively on development of Abbreviated New Drug Applications (ANDAs) for filing with US FDA. This is supplemented by product development and dossier development for European and other markets.

2. Benefits derived as a result of the above R&D activities:

As a result of the continuous efforts by your Company's R&D, 7 DMFs and 18 ANDAs were filed by the Company for regulated market entry during the year under review.

The R&D efforts also led to several international and national filings in all facets of R&D, taking the total patent filings in the year 2004-05 to 85. Six patents were granted during the financial year 2004-05. The total number of patent applications filed and maintained cumulatively is 234.

Orchid's state-of-the-art Research & Development (R&D) centre located in Chennai was inspected by the National GLP Monitoring Authority for the Good Laboratory Practices (GLP) certification. This certification covers areas of Physical-Chemical testing, Safety Pharmacology & Pharmaco-kinetic studies, Toxicity studies, Mutagenicity studies and Analytical & Clinical Chemistry testing.

3. Future plan of action.

Your Company is driving growth through a twin strategy of catering to the expanding global generics market and fulfilling the need for enhanced new drug pipeline. In the process, your Company plans to accelerate product development work for regulated markets, in diverse therapeutic groups. Also, working closely with the drug discovery joint venture in the US, your Company would accelerate drug development in the therapeutic areas of anti-diabetes, anti-inflammatory, anti-cancer, anti-obesity and anti-infective drugs.

4. Expenditure on R&D

The R&D outlay is as follows:

(Rs lakhs)

	Year ended 31-3-2005	Year ended 31-3-2004
a) Capital	3262.56	2705.94
b) Recurring	1958.12	1259.11
c) Total	5220.68	3965.05
d) Total R&D expenditure as a percentage of the total turnover & operating income	7.57%	5.56 %

II TECHNOLOGY ABSORPTION, ADAPTATION AND INNOVATION

1. Efforts in brief, made towards technology absorption, adaptation and innovation.

During the year, efforts were made to innovate patentable new processes and products.

2. Benefits derived as a result of the above efforts, e.g. product improvement, cost reduction, product development, import substitution, etc.

R&D efforts led to development of generic products as well as new compounds, under various stages of evaluation, in several therapeutic areas. In particular, initiatives have been taken up for increasing the product line by adding new molecules in the non-penicillin, non-cephalosporin group. Filing of various DMFs and ANDAs in a short span of time and filing of patents mentioned above were also a result of the efforts of your Company's R&D.

Orchid Chemicals & Pharmaceuticals Ltd.

3. Imported technology (imported during the last 5 years reckoned from the beginning of the financial year):

a) Technology	No new technology has been imported by Orchid during the year.
b) Year of import	Not applicable.
c) Has this technology been fully absorbed	Not applicable.
d) If not fully absorbed, areas where this has not taken place, reasons thereof and future plans of action.	Not applicable.

ANNEXURE III – FOREIGN EXCHANGE EARNINGS & OUTGO

a) Activities relating to exports, initiatives taken to increase exports, development of new export markets for products and services, and export plans.

Orchid is operated as a 100% EOU and has a complete range of oral and sterile cephalosporins, both API and formulations covering various generations. With exports spanning more than 75 countries, Orchid has successfully developed new markets. The Company is now diversifying into multiple therapeutic groups. It is establishing new facilities for non-penicillin, non-cephalosporin oral products. The Company has entered into several long-term exclusive arrangements to distribute its oral and sterile antibiotic formulations as well as oral non-penicillin, non-cephalosporin formulations in the regulated market of US. Other than this, there are country-specific and product-specific alliances in place for the regulated markets of Europe and other regions.

b) TOTAL FOREIGN EXCHANGE EARNINGS & OUTGO

		Year ended 31-3-2005	(Rs lakhs) Year ended 31-3-2004
1.	Earnings in Foreign Exchange during the year		
	F.O.B. value of Exports	52004.32	53154.30
	Export of Services (net of TDS)	140.30	249.14
2.	C.I.F. Value of Imports (on cash basis)		
	Raw Materials	23634.83	20367.09
	Capital Goods	2715.73	3487.86
	Spare Parts, Components and Consumables	2043.08	1901.28
3.	Expenditure in Foreign Currency during the year (on cash basis)		
	Travelling Expenses	39.02	42.56
	Interest and Bank Charges	1032.62	906.33
	Technical Know-how fees	–	–
	Consultancy fees	269.94	328.38
	Others	3900.70	3436.20
4.	Dividend Remittances in Foreign Currency during the year		
	Net Dividend	615.85	537.60
5.	Total Foreign Exchange used (2+3+4)	34231.77	31007.30

PARTICULARS OF EMPLOYEES

ANNEXURE IV TO DIRECTORS' REPORT – INFORMATION PURSUANT TO SECTION 217(2A) OF THE COMPANIES ACT, 1956.

A. Employed throughout the year and in receipt of remuneration aggregating Rs 24,00,000 or more per annum.

Name	Age (Yrs)	Designation	Gross Remuneration (Rs lakhs)	Qualification	Experience in years	Date of Joining	Previous Employer & Position held
Dr Bhaktavatsala Rao C *	55	Deputy Managing Director	63.26	B.E., M.Tech, Ph.D	31	19-Aug-98	Ashok Leyland Limited, Dy. General Manager- Corporate Planning
Bhaskara Raju D S	44	Vice President-Business Planning & Development	35.72	B.Com, ACA	22	01-Jul-92	Oman Chemicals & Pharmaceuticals Ltd, LLC, Sultanate of Oman, Finance Manager
Chandrasekharan A R	52	President-Corporate Finance	37.37	B.Com (Hons.), LL.B, ACA, ACS, CAIIB	30	19-Jan-02	Sterlite Industries India Limited – V.P (Finance)
Chandrasekar L	47	Sr. G M – (Internal Audit) & Secretary	25.60	B.Sc., FCA, FCS, DICM, DISA	23	09-Jul-93	Air Command India Limited – DGM Finance & Secretary
Gowrakannth C R	51	Vice President-Works (Alathur)	25.60	B.Tech, DMS	29	06-Aug-98	Arvind Mills Limited - General Manager - Materials
Edna Braganza	43	Vice President-Commercial	33.85	B.Com	22	01-Nov-93	Al Bursaini Group, Sultanate of Oman – Commercial Manager
Dr Gautam Kumar Das	52	President-Technical (Bulk Drugs)	51.78	M.Sc., Ph.D	26	01-Apr-95	Lupin Laboratories Limited, Sr Manager – Process Development
Mani S	45	Vice President-Projects & Engineering	34.27	B.E. (Mechanical)	22	01-Jul-92	Bharat Heavy Electricals Limited - Dy Manager – Projects Management
Dr Om Reddy G	55	President & Chief Scientific Officer	50.91	M.Sc., Ph.D	28	04-Dec-03	Dr Reddy's Laboratories Limited, Senior Vice President
Prasad P S	56	Executive Director & CEO (Formulations)	94.67	M.Pharm	30	02-Sep-02	Dr Reddy's Laboratories Limited, Executive Vice President – Generics
Raghavendra Rao K *	46	Managing Director	166.36	B.Com, PGDM(IIM-A), ACS, AICWAI	26	13-Jul-92	Al Bursaini Group, Sultanate of Oman, Director
Satish Srinivasan **	36	Regional Manager-orth America	44.64	B Pharm, M.S	10	26-Sep-94	-
Dr Sumant Bavikhandi	50	President-Regulatory Affairs & Quality (Bulk Drugs)	33.27	M.Sc., Ph.D	28	04-Mar-02	Ranbaxy Laboratories Limited – G.M. (Quality Operations & GMP's Training)
Vijayaraghavan S	56	Sr. Vice President- Sales & Marketing (Formulations)	37.19	M.Sc-Pharm, DBM	33	27-Apr-01	Tablets India Limited, Marketing Director

B. Employed for part of the year and in receipt of remuneration aggregating Rs 2,00,000 or more per month.

Name	Age (Yrs)	Designation	Gross Remuneration (Rs lakhs)	Qualification	Experience in years	Date of Joining	Previous Employer & Position held
Ashutosh Ojha	48	Country Head (Domestic Formulations)	6.06	B.Pharm , MBA	24	15-Jan-05	Alkem Laboratories Limited, President – Corp Strategy & Business Development
Aniruddh Deshpande	41	General Manager- International Marketing (Formulations)	16.34	B.Sc., MBA	17	24-Dec-01	02-Infotech Solutions Inc , Director – Business Development
Dr Bakshi S K	51	Vice President-Medical Services	5.06	M.B.B.S., MD	25	24-Oct-01	Cadila Pharmaceuticals Limited, Medical Advisor
Chaitanya Desai	44	Sr. General Manager-Works (Aurangabad)	5.45	B.Sc (Chem), B.Sc (Tech	19	22-Jul-00	Max Pharma, Deputy General Manager – Operations
Raghuram N C	45	Vice President-Information Technology	15.93	B.E.	21	05-Apr-01	Ramco Systems Limited, Regional Manager
Rangesh M S	47	Vice President-Human Resources	6.80	B.Sc., PGDPM, BGL, DLL	24	01-Dec-04	Madhvani Group of Companies, Uganda (Africa), Group General Manager
Ravikumar S **	36	Regional Head-CIS & Eastern Europe	18.35	B.Pharm (Hons)	14	15-Oct-04	Ranbaxy Laboratories Limited, Country Head - Russia
Dr.Shiv Kumar Agarwal	52	Sr. Vice President-NDD	28.75	M.Sc., Ph.D	30	31-Jul-01	Wockhardt Research Centre – Head – Medicinal Chemistry
Dr Sriram Rajagopal	49	Vice President-Biology	20.84	M.Sc., Ph.D	24	21-Jun-04	Dr Reddy's Laboratories Limited, Research Director
Umesh D Kapre	47	Sr. General Manager-Works (Aurangabad)	18.45	B.Tech	23	19-Jul-04	Ranbaxy Laboratories Limited, Senior Manager
Vaidyanathan S	53	Vice President-Human Resources	23.12	B.Sc., PGDPM & IR	30	06-Mar-00	GM (Peru) International Limited – Vice President – HR
Vasudevan B	51	President-API (Manufacturing)	21.18	M Tech	27	15-Jul-04	Ranbaxy Laboratories Limited, Director – Manufacturing

NOTES :

1. Gross Remuneration includes salary, house rent, bonus,/ incentive and other perks like medical reimbursement, leave travel assistance, Company's contribution towards provident fund etc.;
2. All appointments are in terms of respective letters of appointment and applicable Company's rules and regulations except in the case marked* whose appointments are contractual
3. None of the employees mentioned in the list is a relative of any Director of the Company.
4. ** Working overseas, remuneration paid in foreign currency has been converted into Indian Rupees.

OCP0000377

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Orchid Chemicals & Pharmaceuticals Ltd.

CORPORATE GOVERNANCE
ANNEXURE V TO THE DIRECTORS' REPORT

1. Company's Philosophy on Code of Corporate Governance

Orchid, right from its inception has been committed to the highest standards of corporate governance practices. The Company believes that a strong corporate governance policy is indispensable to healthy business growth and resilient and vibrant capital markets, besides being an important instrument of investor protection. Good corporate governance provides an appropriate framework for the Board and the Management fulfill the objectives that are in the interests of the Company and the shareholders. Orchid complies with the Corporate Governance code enshrined in Clause 49 of the Listing Agreement.

2. Board of Directors

The Chairman of the Board is a non-executive, independent Director. The Board has a composition of two executive Directors and nine non-executive Directors. Six out of eleven directors are independent directors.

Composition and category of Directors as of March 31, 2005 is as follows:

S No	Name(s) of Director(s)	Category	Number of Directorships held in other Indian companies	Number of Board Committee memberships held in other companies
1	Shri R Narayanan	Non-Executive – Independent	9	4
2	Shri K Raghavendra Rao	Promoter & Executive Director	2	None
3	Dr C Bhaktavatsala Rao	Executive Director	1	None
4	Dr M R Girinath	Non-Executive – Independent	None	None
5	Dr I Seetharam Naidu	Non-Executive – Independent	None	None
6	Shri Mahendra Kumar Chouhan (IDBI nominee)	Non-Executive – Independent	1	1
7	Shri Deepak Vaidya	Non-Executive	11	6
8	Dr Bishwajit Nag	Non-Executive – Independent	None	None
9	Dr Anzaghi Piergiorgio	Non-Executive – Independent	None	None
10	Shri Sanjay K Sehgal	Non-Executive	2	3
11	Dr Francis Pinto	Non-Executive	1	1

Attendance Record of the Directors

Four Board Meetings were held during the year from April 01, 2004 to March 31, 2005. The dates on which the meetings were held are as follows: April 25, July 28, October 20 in 2004 and January 20 in 2005. The attendance records of all Directors are as under:

Name(s) of Director(s)	No. of Board Meetings		Last AGM Attendance (Yes/No)
	Held	Attended	
Shri R Narayanan	4	3	Yes
Shri K Raghavendra Rao	4	4	Yes
Dr C Bhaktavatsala Rao	4	4	Yes
Dr M R Girinath	4	3	Yes
Dr I Seetharam Naidu	4	4	Yes
Shri Deepak Vaidya	4	2	No
Shri Mahendra Kumar Chouhan	4	3	No
Dr Anzaghi Piergiorgio	4	3	Yes

Name(s) of Director(s)	No. of Board Meetings		Last AGM Attendance (Yes/No)
	Held	Attended	
Shri Sanjay K Sehgal	4	4	Yes
Dr Bishwajit Nag	4	4	Yes
Dr Francis Pinto	4	2	Yes

3. Audit Committee

The Company constituted an Audit Committee consisting of non-executive Directors during 1998.

Terms of Reference of the Audit Committee include a review of:–

a. financial statements before submission to the Board.
b. draft financial statements and auditors' report (before submission to the Board).
c. accounting policies and practices.
d. risk management policies and practices.
e. compliance with stock exchange and legal requirements concerning financial statements.
f. related party transactions.
g. internal control systems and internal audit reports and their compliance thereof, and recommending the appointment of Auditors and fixing their Audit fee.

Four meetings were held during the year from April 01, 2004 to March 31, 2005. The said meetings were held on April 25, July 28, October 20 in 2004 and on January 20 in 2005.

The constitution of the Committee and the attendance of each member of the Committee as on March 31, 2005 are given below:

Name	Category	No. of Meetings	
		Held	Attended
Shri R Narayanan, Chairman	Non-Executive – Independent	4	3
Dr M R Girinath	Non-Executive – Independent	4	3
Dr I Seetharam Naidu	Non-Executive – Independent	4	4
Shri Deepak Vaidya	Non-Executive	4	2
Shri Mahendra Kumar Chouhan	Non-Executive – Independent	4	3
Shri Sanjay K Sehgal	Non-Executive	4	4

The Company Secretary is the Secretary of the Audit Committee.

4. Remuneration Committee

The Remuneration Committee determines and recommends to the Board of Directors, remuneration payable to the Executive Directors. The Board of Directors approves the remuneration to the Executive Directors on the basis of their performance as well as Company's performance, subject to consents as may be required.

The Non-Executive Directors are not paid any remuneration except for the sitting fees for attending the Board Meetings / Committee Meetings.

The resolutions for the appointment and remuneration payable including commission to the Executive Directors are approved by the shareholders of the Company.

The remuneration to the Executive Directors consists of a fixed salary and other perquisites. The Leave Travel allowance is paid as per the Company rules. Provident Fund and Superannuation are provided for as per the Company's policy. Wherever applicable the perquisites are considered a part of remuneration and taxed as per Income Tax laws. The commission recommended by the Remuneration Committee to the Board is paid to the Managing Director in accordance with the provisions of the Companies Act, 1956.

The Remuneration Committee comprises Shri R Narayanan, Dr M R Girinath, Dr I Seetharam Naidu, Shri Deepak Vaidya, Shri Mahendra Kumar Chouhan and Shri Sanjay K Sehgal, all Non-Executive Directors. The Committee deals with all elements of remuneration package, stock options, service contracts, etc. of all whole-time executive Directors. One meeting of Remuneration Committee was held on April 25, 2004 and four directors were present in that meeting.

Details of remuneration paid to Directors are given below: Rs lakhs

Name(s) of Director(s)	Remuneration paid during the Year 2004-2005			
	Salary	Commission/ Bonus /Incentive	Sitting fees	Total
Shri R Narayanan	—	—	3.60	3.60
Shri K Raghavendra Rao	128.26	38.10	—	166.36
Dr C Bhaktavatsala Rao	63.16	0.10	—	63.26
Dr M R Girinath	—	—	1.20	1.20
Dr I Seetharam Naidu	—	—	1.80	1.80
Shri Deepak Vaidya	—	—	0.80	0.80
Shri Mahendra Kumar Chouhan	—	—	1.80	1.80
Dr Anzaghi Piergiorgio	—	—	0.60	0.60
Shri Sanjay K Sehgal	—	—	2.20	2.20
Dr Bishwajit Nag	—	—	0.80	0.80
Dr Francis Pinto	—	—	0.40	0.40

5 Share Transfer and Investors' Grievance Committee

The Company's shares are compulsorily traded in dematerialised form. The Committee has met once a month considering the volume of transactions in the physical segment. During the year 2004-2005 the Committee met 12 times on April 30, May 28, June 24, July 20, August 27, September 27, October 23, November 22, December 21 in 2004 and January 24, February 23, March 28 in 2005.

Name(s) of Director(s)	No. of Meetings	
	Held	Attended
Shri R Narayanan, Chairman	12	9
Shri K Raghavendra Rao, MD	12	12
Dr C Bhaktavatsala Rao, DMD	12	12

The Board has designated Shri L Chandrasekar, Sr. G.M – (Internal Audit) & Secretary as Compliance Officer.

The number of Shares received for transfers in Physical form after the Share Transfer Committee meeting held in March i.e. March 28, 2005 pending as at 31st March, 2005 amounted to 300 shares. These were processed and transferred during the month of April 2005.

The following table shows the nature of complaints received from shareholders during 2004-2005 and 2003-2004, all of which have been resolved within one month.

S No	Nature of Complaints	Received & Answered	
		2004-2005	2003-2004
1.	Correspondence regarding loss of Shares / issue of duplicate certificates	62	29
2.	Non-receipt of Share Certificates	8	6
3.	Non-receipt of dividend warrants	51	59
4.	Revalidation of dividend warrants	410	321
5.	Complaints from SEBI, Stock Exchanges & Govt. Departments	9	2
	TOTAL	540	417

6 Details of Annual / Extraordinary General Meetings

Location and time of General Meetings held in past 3 years

Year	AGM /EGM	Location	Date	Time
2004	AGM	The Music Academy Main Hall, Old No.306, New No.168, TTK Road, Chennai 600 014.	28/07/2004	10.30 A.M.
2004	EGM	Satguru Gnanananda Hall (Narada Gana Sabha), No.314 (Old No.254), TTK Road, Chennai 600 018.	10/04/2004	10.30 A.M.

Year	AGM /EGM	Location	Date	Time
2003	AGM	Kamaraj Memorial Hall, New No.492, Old No.573, 574-A, Anna Salai, Chennai 600 006.	25/07/2003	10.00 A M
2002	AGM	Sathguru Gnanananda Hall (Narada Gana Sabha) No.314 (Old No.254), TTK Road, Chennai 600 018.	29/07/2002	10.30 A.M

All the resolutions including the special resolutions set out in the respective Notices were passed by the Shareholders. None of the resolutions passed at the above meetings were required to be passed through postal ballot.

7 Disclosures

- No transaction of material nature has been entered into by the Company with related parties i.e. Directors or Management, their subsidiaries or relatives conflicting with the Company's interest.
- There were no instances of non-compliance by the Company on any matter related to capital markets during the last three years. Hence, there have been no penalties, strictures imposed by SEBI / Stock Exchange or any other statutory authorities against the Company.

8 Means of Communication

- Financial Results are published by the Company in Economic Times and Dinamani / Dinamalar
- The results are also displayed in URL namely www.orchidpharma.com. Any official news releases are also updated in the site.
- Two presentations were made to analysts and media on November 8, 2004 at Hyderabad and on March 9, 2005 at Mumbai. The presentation materials are available in the Company's website at www.orchidpharma.com.

9 General Shareholder Information & Management Discussion and Analysis

Appended to this Report.

10 Auditor's certificate on compliance of conditions of Corporate Governance

Certificate from the Auditors is enclosed along with this report.

NON-MANDATORY REQUIREMENTS

11 Chairman's Office

The Company maintains a office for the Chairman at its Registered Office at 'Orchid Towers', 313, Valluvar Kottam High Road, Nungambakkam, Chennai – 600 034 and also reimburses the expenses incurred in performance of his duties.

12 Remuneration Committee

The Company has constituted a Remuneration Committee. Terms of Reference of the Committee have been described in serial no.4 herein above.

13 Information to Shareholders

The Quarterly financial results are published in the newspapers as mentioned in serial no.8 above. The results are also displayed on the web site of the Company and are not separately circulated to the shareholders.

AUDITORS' CERTIFICATE ON CORPORATE GOVERNANCE

To
The Members of
Orchid Chemicals & Pharmaceuticals Limited

We have examined the compliance of conditions of Corporate Governance by Orchid Chemicals & Pharmaceuticals Limited (the Company), for the year ended on 31st March 2005, as stipulated in Clause 49 of the Listing Agreement of the said Company with the stock exchanges.

The compliance of conditions of Corporate Governance is the responsibility of the management. Our examination was limited to procedures and implementation thereof, adopted by the Company to ensure the compliance with the conditions of the Corporate Governance. It is neither an audit nor an expression of opinion on the financial statements of the Company.

In our opinion and to the best of our information and according to the explanations given to us, we certify that the Company has complied with the conditions of Corporate Governance as stipulated in Clause 49 of the above-mentioned Listing Agreement.

We state that in respect of investor grievances received during the year ended 31st March 2005, no investor grievances are pending against the Company for more than one month as per the records maintained by the Company and presented to the Investor Grievances/Share Transfer Committee.

We further state that such compliance is neither an assurance as to the future viability of the Company nor the efficiency or effectiveness with which the management has conducted the affairs of the Company.

For SNB ASSOCIATES
Chartered Accountants

(S LAKSHMANAN)
Partner
Membership No. 20045

Place: Chennai
Date : April 27, 2005

Orchid Chemicals & Pharmaceuticals Ltd.

ANNEXURE VI

Details of Options granted to employees under ORCHID – ESOP 1999 Scheme.

♦ Options granted	♦ During the year 2003-2004 – 3,07,925 options were granted ♦ In the year 1999-2000 – 6,00,000 options were granted. The above Options are convertible into equity share of Rs 10/- each.
♦ The pricing formula	♦ 1999-2000 – Rs 243.35; 2003-2004 – Rs 252.00, the price being the closing price of shares of Orchid on November 22, 1999 and January 20, 2004 respectively, the date on which the options were granted by the Compensation Committee of the Board of Directors.
♦ Options Vested during the year	The entire 3,07, 925 options granted in Jan' 2004 have vested during the year.
♦ Options exercised during the year	10,125
♦ Total no. of shares arising out of Exercise of options	10,125
♦ Options lapsed	2,88,975 options, out of the total options of 9,07,925 options granted.
♦ Variations of terms of Options	NIL
♦ Money realized by exercise of options	Rs 24.90 lakhs
♦ Total no. of options in force	6,08,825 options
♦ Employee wise details of options granted to	
i) Senior Managerial Personnel	Details of options granted to Senior Managerial Personnel

S. No	Name	Cumulative options granted so far
1	Dr C Bhaktavatsala Rao	20000
2	Mr R S Prasad	15000
3	Dr G K Das	19400
4	Mr D S Bhaskara Raju	18000
5	Mr C R Dwarakanath	7000
6	Ms Edna Braganza	18000
7	Mr S Mani	18000
9	Mr L Chandrasekar	14000

ii) Employees holding 5% or more of the total number of options granted during the year	NIL
iii) Employees who were issued shares equal to or exceeding 1% of the issued capital	NIL
♦ Consideration received against the no. of shares issued	NIL
♦ Earnings per share (Diluted)	Rs 9.05 (not annualised)
♦ Where the Company has calculated the employee compensation cost using the intrinsic value of the stock options, the difference between the employee compensation so computed and the employee compensation cost that shall have been recognized if it had used the fair value of the options, shall be disclosed. The impact of this difference on profits and on EPS of the company shall also be disclosed.	The company has granted the options to the employees on the closing price of shares of Orchid on November 22, 1999 and January 20, 2004 and not on the Intrinsic value. Hence, the difference between the employee compensation and the employee compensation cost that shall have been recognized if it had used the fair value of the options, may not be applicable.
♦ Weighted – average exercise price	The weighted average exercise price (26 weeks preceding the date of grant) was Rs 183.42 for the options granted on November 22, 1999 and Rs 199.31 for the options granted on January 20, 2004.

GENERAL SHAREHOLDERS' INFORMATION

1 Dates of book closure : July 15, 2005 to July 18, 2005 (both days inclusive)

2 Venue of the Annual General Meeting (AGM) : Kamaraj Memorial Hall, New No. 492, Old No.573,574-A, Anna Salai, Chennai 600 006, Tamil Nadu, India.

3 Time and Date of AGM : 10.30 A.M. on Monday, July 18, 2005

4 Financial Calendar

Financial reporting for

- Quarter ending June 30, 2005 : Third week of July 2005
- Quarter ending September 30, 2005 : End of October 2005
- Quarter ending December 31, 2005 : End of January 2006
- Year ending March 31, 2006 : End of April 2006

5 Dividend Payment Date : Fourth week of July 2005

6 The equity shares of Rs.10/- each are listed at :

Madras Stock Exchange Limited
Exchange Building, Post Box No.183
New No.30 (Old No.11), Second Line Beach
Chennai - 600 001, Tamil Nadu, India
Tel: 91-44-25228951, 25224382, 25224392, Fax: 91-44-25244897

National Stock Exchange of India Limited
Regd Office: "Exchange Plaza", Bandra-Kurla Complex
Bandra (East), Mumbai - 400 051, Maharashtra, India
Tel: 91-22-26598100, 56418100, Fax: 91-22-26598237 / 38, 26598120

The Stock Exchange, Mumbai
New Trading Ring, Rotunda Building
Phiroze Jeejeebhoy Towers, Dalal Street, Fort
Mumbai - 400 001, Maharashtra, India
Tel: 91-22-22721233, 22721234,
Fax: 91-22-22723677, 22722082 / 3132

7 Listing Fees : Paid for all the above Stock Exchanges for 2004-2005 and 2005-2006

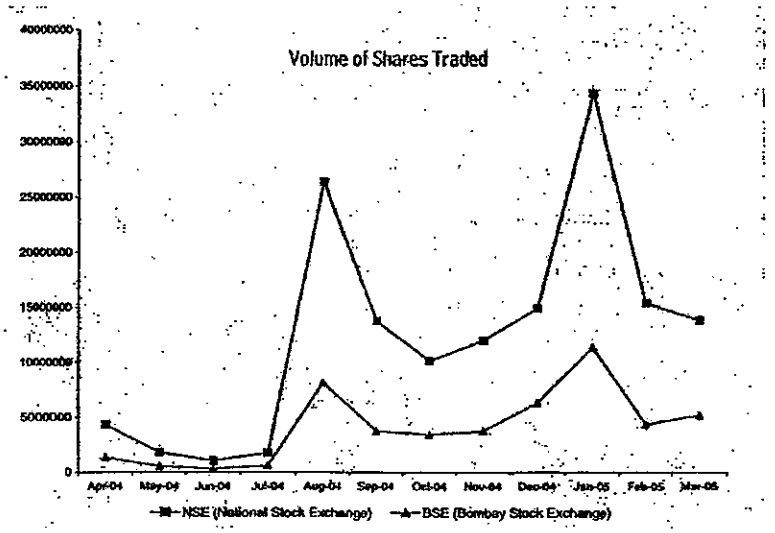
8 Registered Office : "Orchid Towers", No: 313, Valluvar Kottam High Road, Nungambakkam, Chennai - 600 034, Tamil Nadu, India.

9 Stock Market data

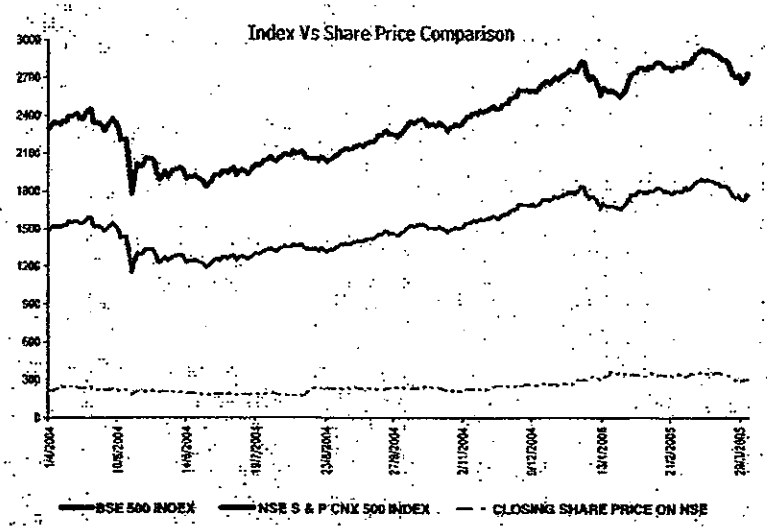
a) Monthly high and low quotations along with the volume of shares traded at NSE and BSE for 2004-2005 are:

Month	NSE			BSE		
	High (Rs)	Low (Rs)	Volume (Nos)	High (Rs)	Low (Rs)	Volume (Nos)
Apr-04	243.00	214.35	4329132	243.40	214.15	1329353
May-04	224.10	177.90	1785595	224.25	179.10	544164
Jun-04	205.80	176.55	1038379	205.80	175.95	300260
Jul-04	194.70	178.25	1747124	193.75	178.95	603523
Aug-04	240.30	169.90	26374893	240.60	169.70	8182850
Sep-04	243.45	221.30	13769854	243.55	221.40	3770735
Oct-04	251.40	209.75	10144704	251.45	209.05	3432827
Nov-04	256.65	210.50	11999557	256.80	210.25	3759371
Dec-04	295.80	247.35	14924746	295.75	247.30	6302930
Jan-05	362.00	290.50	34313835	361.50	290.45	11366091
Feb-05	358.70	325.65	15399740	360.70	325.50	4381022
Mar-05	356.20	288.75	13827552	355.60	289.40	5177180
TOTAL			149655111			49150306

b) Graphical representation of Volume of Shares traded of Orchid during April 2004 – March 2005



c) Comparison of broad based indices with share price of Orchid



10 Stock Exchange Security Code

Madras Stock Exchange Ltd	OCL
The Stock Exchange, Mumbai	524372
National Stock Exchange of India Ltd	ORCHIDCHEM
Depository ISIN No.	INE191A01019

11 Distribution of Shareholding as on:

No. of Equity Shares held	31st March 2005			31st March 2004		
	No. of Shares	No. of Shareholders	% of Shareholders	No. of Shares	No. of Shareholders	% of Shareholders
1-500	3566402	28959	92.70	4478921	33906	92.86
501-1000	1001377	1242	3.98	1223400	1535	4.20
1001-2000	782039	506	1.62	903670	601	1.65
2001-3000	483270	185	0.59	470974	183	0.50
3001-4000	266043	74	0.24	255753	72	0.20
4001-5000	307234	64	0.20	265438	56	0.15
5001-10000	734936	100	0.32	645213	90	0.24
10001 & above	26990618	109	0.35	24138550	74	0.20
TOTAL	34131919	31239	100.00	32381919	36517	100.00

12 Dematerialization of Shares

The shares of the Company are in compulsory demat segment and are available for trading in the depository systems of both the National Securities Depository Limited and Central Depository Services (India) Limited. Shares dematerialised upto 31-03-2005 are:

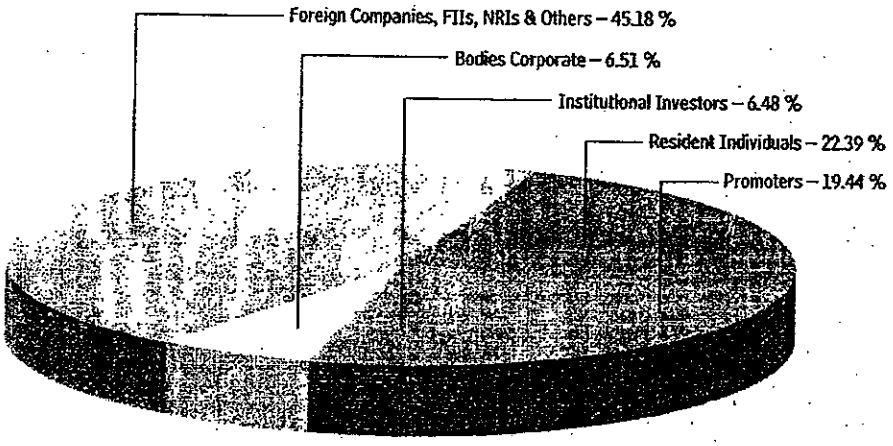
No. of Shares	% of Shares	No. of Shareholders	% of Shareholders
33643756	98.57	27884	89.26

13 Shareholding Pattern as on March 31, 2005:

CATEGORY	NO OF SHARES HELD	PERCENTAGE OF SHAREHOLDING
A PROMOTERS' HOLDING		
1 Promoters		
– Indian Promoters	6635954	19.44
– Foreign Promoters	Nil	Nil
2 Persons acting in concert	Nil	Nil
Sub-Total (1+2)	6635954	19.44
B NON-PROMOTERS' HOLDING		
3 Institutional Investors		
a Mutual Funds and UTI	226683	0.66
b Banks, Financial Institutions, Insurance Companies (Central / State Govt. Institutions / Non-Government Institutions)	1984616	5.82
c Foreign Institutional Investors	915600	2.68
Sub-Total (3)	3126899	9.16
4 Others		
a) Private Corporate Bodies	2223321	6.51
b) Indian Public	7641821	22.39
c) NRIs	185978	0.54
d) OCBs	1000	0.00
e) Foreign Companies	14166946	41.52
f) Foreign Collaborators	150000	0.44
Sub Total (4)	24369066	71.40
GRAND TOTAL (1+2+3+4)	34131919	100.00

Orchid Chemicals & Pharmaceuticals Ltd.

SHAREHOLDING PATTERN



14 Legal Proceedings

There are a few pending cases relating to the disputes on the title of the shares. The Company has been made a party to the disputes but these, however, are not material in nature.

15 Share Transfer System

M/s Integrated Enterprises (India) Limited is the Registrar and Share Transfer Agents for servicing activities relating to both Physical and Electronic segments. The Share Transfer Committee met 12 times during the year 2004-2005.

16 Unclaimed Dividends

Pursuant to Section 205 A of the Companies Act, 1956, unclaimed dividends up to and including dividends for the financial year 1996-97 have been transferred to the general revenue account of the Central Government / Investor Education and Protection Fund.

The dividend for the year 1997-98, which remain unclaimed for seven years will be transferred to Investor Education and Protection Fund established by the Central Government under Section 205 C of the Companies Act, 1956. Shareholders who have not encashed their dividend warrants for the said year and thereafter are requested to contact the Company immediately.

17 ECS Mandate

To service its investors better, the Company requests all shareholders who hold shares in dematerialised form to update their bank particulars with their respective depositories immediately. Shareholders holding shares in physical form may kindly forward the bank particulars to our Registrars at the address as given below.

18 The Company's Registrars are:

Integrated Enterprises (India) Limited
2nd Floor, Kences Towers, No.1 Ramakrishna Street
North Usman Road, T.Nagar, Chennai - 600 017, Tamil Nadu, India
Tel: 91-44-28140801 – 03, Fax: 91-44-28142479, E-Mail: yeshalu@iepindia.com

MANAGEMENT DISCUSSION AND ANALYSIS REPORT 2004-05

Introduction

Orchid is an emerging global pharmaceutical company with established research, manufacturing and marketing capabilities. Orchid's business consists of two principal segments; the active pharmaceutical ingredients (or APIs, also called bulk drugs or bulk actives) segment and the formulations (or finished dosage forms) segment. Orchid also undertakes drug discovery activities to help discover new products and molecules which can be patented. Orchid plans to license out new drugs or molecules discovered to multinational pharmaceutical companies for commercialization.

The principal products manufactured are cephalosporins, which are the primary active ingredients in many antibiotic drugs, high-end betalactams (which like cephalosporins are active ingredients in a different class of antibiotic drugs) and nutraceuticals. For fiscal 2005, approximately 87.6% of Orchid's sales was derived from the sale of oral and sterile cephalosporins, and 12.4% from the sale of high-end betalactams, nutraceuticals and other products. Within the cephalosporin range, oral cephalosporins accounted for 73.5% of total cephalosporins revenues and sterile cephalosporins accounted for the remaining 26.5% of total cephalosporins revenues in fiscal 2005.

Orchid presently has two API manufacturing plants and three formulations manufacturing plants in India as well as one API manufacturing plant in China. Orchid has a strong market presence in the less regulated markets like India, China, Latin America, Russia, the CIS countries and the Middle East. Orchid is increasingly focusing on developing the business in the regulated markets like the United States, Europe and Japan through generics or non-branded versions based on non-infringing processes after certain products go off-patent. Orchid also sells its APIs in these regulated markets, based on regulatory approvals for certain specific products. Orchid conducts new drug discovery research in-house and through the joint venture company in the United States, Bexel Pharmaceuticals Inc.

To assist the product-market expansion and entry into the regulated generic markets, Orchid made several significant investments since fiscal 2001. These investments included the acquisition and upgrading of the bulk drugs plant at Aurangabad, which enabled the company to enter into the high-end betalactam segment and establishment of new manufacturing facilities with US FDA compliance at Alathur and Irungattukottai, near Chennai for cephalosporin APIs and formulations respectively, covering both sterile and oral ranges of products. These investments will enable Orchid to sell a larger volume of products, both APIs and formulations, into the regulated markets, achieving higher performance levels from fiscal 2006. Orchid has also invested in upgrading other existing facilities. In addition, Orchid has set up facilities for the manufacture of niche nutraceuticals, both API and formulations, to be marketed as dietary supplements, which are being sold in the US, among other regulated markets.

Orchid acquired the brands, the formulation business and assets of Mano Pharmaceuticals Private Limited (and its affiliate Sali Healthcare Private Limited) in 2003, which enabled Orchid to enter various chronic therapy areas and to enhance the domestic market reach. Orchid also formed a joint venture in China to manufacture sterile cephalosporin APIs for the Chinese market. To establish and expand the drug discovery programmes, Orchid invested in the building of new medicinal chemistry and drug screening laboratories and a modern pre-clinical centre with an animal house at its R&D campus in Sholinganallur, near Chennai and also formed research joint ventures in the United States and Europe. Orchid also invested in setting up a company-wide ERP system and to further develop the IT network.

More recently, Orchid has pressed ahead with a non-penicillin, non-cephalosporin (NPNC) business plan because of its vital importance to power growth from fiscal 2008. As part of this, new NPNC R&D laboratory infrastructure has been created at Sholinganallur and a new NPNC API facility was established at Aurangabad. A pilot plant and formulations facility is being established at Irungattukottai for NPNC formulations and to file ANDAs for this product range.

To provide further impetus to R&D, pharma R&D has been re-located at Irungattukottai as a larger Pharma R&D centre, while a New Drug Discovery Facility has been established in the Sholinganallur R&D campus. A new process validation laboratory will be operational this fiscal.

With these investments and infrastructure, Orchid is poised to achieve significant increase in performance from the current fiscal onwards through regulated market entry and further through diversification of business in terms of multiple therapeutic groups. Select cephalosporin APIs are already exported to the US and generic dosage forms in this product class have commenced to support product launches in the US from July 2005. The generics exports to the regulated markets would be stepped up and further expanded through the addition of products from cephalosporin and other anti-infective categories progressively thereafter and from multiple therapeutic groups from fiscal 2008 onwards.

Results of Operations

The main factors which have significant impact on our results of operation, financial condition and cash flows include the global pharmaceutical demand and supply situation, the emerging potential for drug discovery & development, our capital expenditure and our operating expenses.

Our sales volumes are influenced by the global demand and supply situation for pharmaceuticals. As the entry barriers for sales to regulated market are stringent, companies operating in these markets face lower competition and enjoy higher margins on sales as compared to companies operating in less regulated markets. Our business strategy is aimed at a significant increase in sales of our products to regulated markets in the following years. We have been consciously adopting a strategy of enhancing capabilities, increasing capacities and upgrading technology with the objective of consolidating and growing in non-regulated markets as well as entering the lucrative regulated generics and drug discovery markets.

Orchid registered a turnover and operating income of Rs 689.29 crore for the fiscal year ended March 31, 2005 compared to the previous year's revenues of Rs 713.41 crore. Gross profit before interest, depreciation and taxes was Rs 163.11 crore compared to Rs 150.49 crore last fiscal. After providing for interest of Rs 72.31 crore (Rs 60.67 crore last fiscal) and depreciation of Rs 61.89 crore (Rs 56.84 crore last fiscal) the profit before tax of the Company was Rs 28.91 crore as against the previous year's profit before tax of Rs 32.98 crore. Net profit after tax was maintained at Rs 31.01 crore as against Rs 31.03 crore for the last fiscal despite a reduction in the turnover. The EPS of the Company stood at Rs 9.55 compared to Rs 9.53 last fiscal.

A few highlights of the Company's performance during the year under review include :

- Reaching top slot in ANDA filings in the anti-infectives area in the Indian industry in the very first year of ANDA operations.
- Successful US FDA inspection of Orchid's state-of-the-art cephalosporin generics formulations facility covering various dosage forms ; 9 ANDAs reviewed as part of the inspection.
- Arising from the US FDA inspection, approval for Cefazolin ANDA received this fiscal; more approvals are expected to follow.
- Successful completion of safety, tolerability and limited proof-of-concept human clinical trials on lead anti-diabetic molecule BLX-1002; discussions underway with a few MNCs for possible out-licensing.
- Certificate of Suitability (CoS) approval for a key cephalosporin API received taking cummulative approvals to 9.
- Marketing alliance with Apotex for sterile antibiotic generics extended to the Canadian market.
- Distribution alliance with IVX Animal Health, Inc. (formerly Phoenix Scintific Inc.) for marketing sterile veterinary generic product in US, Canada and Mexico.
- Agreements inked with Alpharma, Par and STADA, reputed global generic players, for marketing select oral non-penicillin, non-cephalosporin formulations in select regulated markets.

Arising from various alliances, 16 antibiotic generic products (15 cephalosporins and 1 betalactam product) and 20 non-cephalosporin, non-penicillin generic products have been tied up for distribution in US, while a few will be distributed additionally in Europe as well.

This fiscal 2005 thus saw the Company cross several milestones related to establishment of high-technology projects, successful US FDA inspection, diversification of product and manufacturing base into finished dosage forms of multiple therapeutic groups and marketing alliances with top-ranking generic firms in US and Europe. The progress achieved in all key operating segments has strongly positioned Orchid as an integrated pharmaceutical company spanning markets across the world.

Supported by the improvements in physical output and product-market mix, we have been able to enhance our margins considerably this fiscal. This has led to increased profitability at the net level.

Bulk Actives Business

Active Pharmaceutical Ingredients Segment

APIs are the principal ingredients for formulations. The Company produces several different APIs for use in pharmaceuticals. The main APIs are in the therapeutic category of antibiotics and primarily include cephalosporins and high-end betalactams. Cephalosporins are broadly categorised into four "generations" ranging from the first to fourth, depending on the molecular structure that is used in their manufacture.

The Company manufactures all four generations of cephalosporins and other APIs including the non-cephalosporin range of products, which comprises of non-cephalosporin betalactam products, penicillin and non-penicillin based products and nutraceuticals.

The API business amounted to 87.6% of the total revenues for fiscal 2005 and cephalosporins amounted to 92.8% of the Company's total API revenues. The following table sets forth revenues of our key APIs for each of fiscal 2004 and 2005:

	2004-05		2003-04	
	Rs lakhs	%	Rs lakhs	%
Cephalosporins	51874	92.77	53959	92.77
Non-cephalosporins, Betalactam and Nutraceuticals	4040	7.23	4210	7.23
Total	55914	100.00	58169	100.00

The Company sells APIs in India and exports them to regulated as well as less regulated markets worldwide. In addition, Orchid also supplies APIs to its formulations segment and the principal

markets to date in this business segment thus include China, Europe, the Middle East, India and Asia Pacific, which together amounted to 87.7% of the segment's revenues. The following table sets forth our API revenues excluding operating income by geographic area for each of fiscal 2004 and 2005.

	2004-05		2003-04	
	Rs lakhs	%	Rs lakhs	%
India	6204	11.10	6875	11.82
Asia Pacific*	7746	13.85	6704	11.52
China and Hong Kong	17441	31.19	20222	34.76
Japan	209	0.37	1434	2.47
Europe	9861	17.64	8694	14.95
Middle East	7775	13.91	7580	13.03
South/Central America	3402	6.08	3496	6.01
North America	1272	2.27	484	0.83
Russia and CIS	1758	3.14	2476	4.26
Rest of the world	246	0.45	204	0.35
Grand Total	55914	100.00	58169	100.00

*other than India, China, Japan, Australia, New Zealand and Hong Kong

The share of USA, Canada and Europe, the principal regulated markets has gone up from 15.78% in 2003-04 to 19.91%, accompanied by a continued diversification of share in other markets.

Formulations Business

Formulations, also referred to as finished dosages, are finished pharmaceutical products ready for consumption by the patient. Branded formulations are those which are sold under Orchid's brand name. The Company's branded formulations in India and other less regulated markets accounted for 12.4% of the total revenue in fiscal 2005.

The Company has consolidated the sale of formulations in India during the year under review, in terms of critical care (antibiotics), cardiovascular, neuro-psychiatry and anti-diabetes divisions. Orchid also markets several niche nutraceuticals along with the above therapies. The Company thus has a mix of acute therapy as well as chronic therapy products.

The Company's revenues from sales of formulations in India were 63.4% of the total formulations sales in fiscal 2005. The sale of domestic formulations would have been higher but for the unsettled conditions in distribution channels in the wake of proposed introduction of Value Added Tax regime and the considerable de-stocking resorted to by wholesalers and stockists. Orchid expects performance in the current fiscal to be better.

Orchid exports its formulations to over 28 countries worldwide and the major export markets for such formulation products are the United States, Russia and CIS countries, Latin America, Africa, the Middle East and Far East Asia. Nutraceutical formulations are largely exported to the United States. The following table sets forth our revenues (without operating income) from formulations by geographic area for each of the fiscal 2004 and 2005.

	2004-05		2003-04	
	Rs lakhs	%	Rs lakhs	%
India	5025	63.41	7592	76.58
Asia Pacific	410	5.17	277	2.80
Europe	360	4.54	131	1.32
Middle East	42	0.53	46	0.47
South/Central America	18	0.23	16	0.16
North America	1150	14.51	1154	11.64
Russia and CIS	685	8.64	475	4.79
Rest of the world	235	2.97	223	2.24
Total	7925	100.00	9914	100.00

In line with the strategy of focussing on high value markets, initiatives have been taken for increased presence in Russia and CIS countries, which has been reflected in a higher sale. Export of formulations to North America comprise SAMe dietary supplement with a steady level of sale. The fiscal 2006 would see the export of generic pharmaceutical products to US in a significant way.

Orchid has gradually increased the number of countries for marketing the formulations by registering its products in various markets around the world. During fiscal 2005, the Company has filed 168 product dossiers (18 ANDAs for US, 2 dossiers each for Europe and Canada and 146 dossiers for emerging markets) in various countries around the world. The total number of product registrations at the end of fiscal 2004-05 was approximately 224 which cover 29 products in 30 countries. The new markets we entered during fiscal 2005 were from Eastern Africa and certain Eastern and Central European countries.

US Generics

Orchid has an end-to-end connected business model, which positions it well in the US generics market in its product class. Integrating and leveraging its infrastructure in the API and formulations businesses with its competencies in developing non-infringing API processes and formulations and making world-class regulatory filings, Orchid is capable of executing its generics strategy for its cephalosporin and other products. During the fiscal under review, Orchid achieved significant progress in its US generics foray. In the very first year of its ANDA activity, Orchid filed 18 ANDAs leading to a top rank in ANDA filings related to cephalosporin and anti-infective products in the country. During 2005-06, Orchid would continue the regulatory momentum in broader product segments.

The Company's state-of-the-art cephalosporin formulations facility located at Irungattukottai, near Chennai has undergone a successful inspection by the US FDA without any "483" observation. As part of the process, 9 Abbreviated New Drug Applications (ANDAs) out of the 18 filed till date were reviewed.

The 9 ANDAs cover various dosage forms of injectables, tablets, capsules and dry syrups.

Orchid has exclusive marketing alliances with global generic majors, Apotex and Par Pharmaceutical, for distribution of its identified cephalosporin generic formulations in the US and with Alpharma, Stada and Par for distribution of select products of diverse therapeutic groups in the US and Europe.

Orchid has received orders from its market partners for export of cefazolin injectable vials, ceftriaxone injectable vials, cephalexin capsules and veterinary injectable vials. Manufacturing and supply chain activities have been initiated, based on the approval received from US FDA, and other approvals expected, given the long lead time and the need to be present with specific products on the planned launch dates.

Research & Development

The competitive environment in less regulated markets including India is changing significantly with most countries having already moved towards a product patent recognition regime. This has the effect of shrinking the window of opportunity in terms of reverse engineering to achieve new product launches in such markets.

In addition, multi-national pharmaceutical corporations are becoming increasingly open to in-licensing validated new drug compounds for strengthening their new drugs pipeline for their markets. A large unmet need for enhancing new drug pipeline thus gives us a major opportunity.

Proactively, Orchid has created facilities and joint ventures to support drug discovery and development capabilities. Orchid's drug discovery efforts will help the company achieve a niche presence based on innovation in such markets. However, the Company needs to incur the required expenses on drug discovery and development before it can have a commercialization opportunity.

Orchid's R&D expenses comprise both capital and revenue items, which consist of regular operating expenses, project expenses and expenses for operation of research and infrastructure programmes. While R&D revenue expenditures are expensed when incurred, the R&D capital expenditures are added to assets and depreciated. Total R&D expenses constituted 5.6% and 7.6% of our total revenues for fiscal 2004 and fiscal 2005 respectively. The increase in the R&D expense is attributable to increased development of non-infringing processes, increased R&D activities for regulated markets and investments and expenses for drug discovery including investments in our drug discovery venture in US, Bexel Pharmaceuticals Inc. We have completed our cash contribution of US$ 8 million and services contribution of US$ 2 million for our 50% stake in the JV as envisaged over a three year period beginning July 2002. Bexel has since successfully completed safety, tolerability and proof-of-concept human clinical trials of its anti-diabetes molecule BLX-1002 in Europe and is in dialogue with multi-national companies for possible out-licensing. Bexel is also conducting pre-clinical studies on its anti-obesity and anti-inflammatory molecules.

Our research operations in India, United States and Europe are engaged in advanced drug discovery and higher order applied chemistry work. Drug discovery operations typically take a few years to yield results. Our consolidated revenues therefore bear the impact of our investments and contributions of in-house R&D and drug discovery programmes.

Financial Analysis

Key parameters of financial performance in 2004-05 as compared to 2003-04 are summarized below.

Rs lakhs

S.No	Particulars	2004-05	2003-04	Growth (%)
1	Total Sales & Operating Income	68929	71341	(3.38)
2	EBIDTA	16311	15049	8.38
3	PBIT	10122	9365	8.08
4	PBT	2891	3298	(12.34)
5	PAT	3101	3103	(0.06)
6	EBIDTA Margin (%)	23.66	21.09	12.20
7	PBIT Margin (%)	14.68	13.13	11.80
8	PBT Margin (%)	4.19	4.62	(9.31)
9	EPS-Annualised (Rs per Share) – Basic	9.53	9.58	(0.52)
10	EPS before deferred tax-(Annualised (Rs per Share) – Basic	8.89	9.58	(7.20)
11	Value Added per employee (Rs Lakhs)	7.46	7.71	(3.24)

Despite increases in the material, employee, power and fuel costs and in our other operating expenses, consequent to higher level of operations and other specific contributory factors (which include strengthening of the Rupee against the US$ and expenses to enable entry into specific markets), EBIDTA increased by 8.38% to Rs 163.11 crore as compared to Rs 150.49 crore for the previous fiscal.

The total EBIDTA margin as a percentage of our total income grew to 23.66% from 21.09%, thus registering 12.20% growth. Optimisation of product market-mix and cost management have contributed to the enhanced operating margins. The PBIT stood at Rs 101.22 crore compared to Rs 93.65 crore for the previous fiscal, thereby registering a growth of 8.08%. Total PBIT margin as a percentage of our total income grew to 14.68% from 13.13% thus registering 11.80% growth. The PBT was lower at Rs 28.91 crore compared to Rs 32.98 crore due to the higher interest cost. The PAT was however maintained at the same level as in the previous fiscal.

Risk Management

Like all businesses, the pharmaceutical industry has its risks. The risks that the company faces may be classified as risks relating to the business, the currency and capital markets.

The company has appropriate strategies to manage the risks. The strategies relating to key business risks are detailed herein.

Product-market factors

The Company currently derives a significant portion of its revenue from limited therapeutic areas which include cephalosporins, high-end betalactams and nutraceuticals. The Company currently also derives a significant portion of its revenues from less regulated markets. The Company is implementing strategies to diversify its product range and enter into regulated markets. However, any material adverse developments in such product-market strategies could have an adverse material effect on the revenues and profitability. An increase in the intensity of competition in any of its products and markets could also have a material adverse impact on the performance of the Company.

Supply Factors

The Company depends on its suppliers for its key raw materials, intermediates and other packaging materials. As the Company enters regulated markets, some of these inputs need to be sourced from US FDA approved suppliers as well. While the Company has contractual arrangements in place with the existing suppliers and also has alternative suppliers to cater to supply deficiencies, the possibility of any supply constraints affecting the Company's performance cannot be ruled out.

Intellectual Property

While the Company's business has traditionally focused on non-patented products, its regulated market strategy is based on introducing generic versions after the products go off-patent, based on non-infringing processes. The Company also files and seeks to obtain patents for new drugs and novel drug delivery systems under development. Patents are therefore likely to become more significant to the Company in the future. The success of the Company depends, in part, on its ability to protect trade secrets and other proprietary information and obtain patents and operate without infringing on the proprietary rights of others. The Company's competitors may have filed patent applications, or may hold issued patents, relating to products or processes that compete with those the Company itself is developing or seeking to protect, or their patents or their litigation may impair the ability of the Company to do business in a particular geographic area.

The Company takes all reasonable steps to ensure that its products, including the generic products manufactured and sold by it, do not infringe valid third-party intellectual property rights. Nevertheless, innovators and other companies try to assert patent and other intellectual property rights in order to delay or prevent generic competition. As a result, the Company can become involved in extensive litigation regarding its products. Such events could adversely affect the financial position, results of operations or liquidity of the Company.

Historically, the Company has relied on trade secrets, know-how and other proprietary information as well as requiring its principal employees, vendors and suppliers to sign confidentiality agreements. However, these confidentiality agreements may be breached, and the Company may not have adequate remedies for any breach. Third parties may otherwise gain access to its proprietary information or may independently develop substantially equivalent proprietary information.

Governmental regulations

Governmental authorities including the US FDA, heavily regulate the manufacture of pharmaceutical products. These relate, among others, to approvals to manufacture and market pharmaceutical products, controls on marketing, pricing and promotion of pharmaceutical products, environmental, safety and health regulations and post-approval changes. If the Company or its third party suppliers fail to receive government approvals or fail to comply fully with such regulations, there could be a government-enforced shut-down of such production facilities, which in turn could lead to product shortages. Although the Company seeks to take necessary precautions to avoid the above risks and it has in place appropriate systems, procedures and operating practices to mitigate such risks, its operations may be materially adversely affected if such events were to occur.

Fire and other natural calamities

The Company uses flammable materials and solvents in its manufacturing processes and is therefore subject to the risk of loss arising from fires. Although the Company has implemented industry acceptable risk management controls at its manufacturing locations and continuously seeks to upgrade them, the risk of fire associated with these materials cannot be completely eliminated. In addition to fire, natural calamities such as floods and earthquakes could have a harmful impact on the Company's operations. While the Company's insurance coverage for damages to its properties and disruption of its business due to these events is adequate, it may not be certain that it would be sufficient to cover all of its potential losses. If any of its manufacturing facilities were to be damaged as a result of fire or other natural calamities, it would temporarily reduce manufacturing capacity and harm the Company.

Product patent regime

As India did not, prior to 1 January 2005, grant or recognise pharmaceutical product patents, the Company was able to develop and sell its products in less regulated markets which did not similarly recognise product patents, while those products continue to remain on patent in regulated markets. The Company will not, like other Indian pharmaceutical companies, henceforth be able to sell in India or elsewhere pharmaceutical products whose patents are recognised in India, unless and until these patents expire or are invalidated. While this is addressed by

the strategy of the Company to increasingly focus on generic products in regulated markets, the reduced opportunity to reverse-engineer patented products could affect potential growth in less regulated markets.

Regulated markets

Commencing in July 2005, the Company intends to progressively enter a number of markets which in the pharmaceutical industry are considered to be heavily regulated, including the United States, for the sale and distribution of generic formulations and APIs. The Company has made substantial investments for establishing and upgrading its manufacturing facilities so that they comply with the standards set by the US FDA and other regulatory authorities. The Company has demonstrated an aggressive capability for filing DMFs and ANDAs and securing US FDA approvals. However, any delays in filing future DMFs and ANDAs, or in the inspection and approval of the Company's facilities and products by the US FDA or other applicable regulatory authorities, could adversely affect this strategy and the timing thereof, which in turn could adversely affect the results of operations and prospects of the Company.

The costs involved in entering the regulated markets may be higher than expected and the Company may face significant competition in these regions. Unanticipated price erosion could adversely reduce its sales revenue and profit potential. As a result of these and other changes in the business environment of the Company, it cannot be certain that its business model will continue to be as successful as anticipated.

Product liability claims

Like all pharmaceutical companies, the Company faces the risk of loss resulting from, and the adverse publicity associated with, product liability lawsuits, whether or not such claims are valid. It is likely the Company cannot avoid such claims. Even unsuccessful product liability claims could require the Company to spend money on litigation, divert management's time, damage its reputation and impair the marketability of its products. In addition, although the Company has adequate product liability insurance coverage, it cannot be certain that its insurance will, in fact, be sufficient to cover such claims or its policy limits would be sufficient to cover such claims or that it will be able to maintain adequate insurance coverage in the future at acceptable costs. A successful product liability claim that is excluded from coverage or exceeds the Company's policy limits could require it to pay substantial sums. In addition, insurance coverage for product liability may become prohibitively expensive in the future.

Marketing Arrangements

The Company will need to rely on its marketing arrangements and tie-ups with partners in regulated markets for the sale and distribution of some of its generic products. The Company is exposed to the risk of its partners failing to adhere to the standards set for them in respect of minimum distribution and sales which in turn could affect the net sales and revenue of the Company. The Company's products are marketed in some countries through joint ventures, branch offices and subsidiaries and representative offices. The Company also markets and distributes its products through third parties by way of marketing and agency arrangements, and depends on third party distributors in all its export markets. As a result, many of the variables that may affect the revenue and net income of the Company are not exclusively within its control when it enters into arrangements like these.

Exchange rate fluctuations

The financial statements of the Company are prepared in Rupees. A substantial portion of the Company's net revenue and most of the imports are incurred in foreign exchange and in particular US dollars. The Company's exposure to exchange rate fluctuations is hedged in terms of its exports and imports. Although the Company naturally hedges a portion of the resulting net foreign exchange position through the use of forward exchange contracts or derivatives, the Company is still affected by fluctuations in exchange rates among the US dollar, the Rupee and other currencies. The Company is particularly affected by fluctuations in the exchange rate between the US dollar and the Rupee. Any significant fluctuation in exchange rates may affect the profitability of the Company.

Internal Control Systems & their Adequacy

The Company has introduced Standard Operating Procedures (SOPs) in all the important functions covering the day-to-day operations of the business. In order to avoid duplication of work, many of the SOPs are designed to meet the GMP / FDA /ISO /Management or any other Statutory requirements. The Company continuously monitors compliance to the procedures and introduces new systems from time to time, wherever necessary. The introduction of an integrated SAP ERP across the organization (for all the business areas and for all functions) has, to a great extent, set uniform practices.

The highlights of the Internal Audit reports are placed before each audit committee meeting along with the recommendations and responses of the Management. The members of the Board deliberate and advise the Management on improvements /compliance. Apart from above, the statutory auditors also present their concerns to the members of the Board for improvements or developments.

Human Resources

As at 31 March 2005, the Company had approximately 2900 team members, which included scientific and technical personnel and employees located at its several manufacturing and research facilities including its joint ventures and subsidiaries, besides corporate and managerial personnel and sales staff.

A high point of the human resource initiatives of the Company involved developing and training of a new technical and manufacturing organisation at the US FDA compliant finished dosages forms complex at Irungattukottai in line with completion of facilities and ramping up of regulatory activity. Several novel development programmes were undertaken to institutionalise high levels of quality and regulatory compliance at the site. Similarly significant additions to scientific resource base were achieved in the R&D centre to support enhanced activity in process research, development of multiple therapeutic products and new drug discovery, among others.

The year also saw an increased focus on employee welfare together with programmes reinforcing the team spirit and values of the employees in the organisation. The employees across the locations are intensively trained on GMP, SOP, safety, environment and health consciousness and also monitored for their continuous adherence to the practices.

Business Environment and Prospects

Orchid operates in the global pharmaceutical industry. Orchid's business model is focused on development, manufacturing and marketing of active pharmaceutical ingredients and formulations for global markets. Orchid also undertakes drug discovery and development. Orchid anticipates major growth from entry into the regulated markets with generic finished dosage forms of a diversified product range. Participation in the global drug discovery space would provide further upside as new chemical entities (NCEs) are discovered and outlicensed by Orchid upon necessary development and evaluation.

The size of the global pharmaceutical industry is estimated to be US$ 518 billion in 2004 as per the latest IMS estimates. The industry has been growing at 7 to 9 per cent over the last few years. North America is the largest and fast growing pharmaceutical market in the world with a retail sale of US$ 248 billion (48%). European Union accounts for US$ 144 billion (28%) while Japan accounts for US$ 58 billion (11%). The premier regulated markets of the world i.e., US, EU and Japan account for US$ 450 billion sales, constituting as much as 87% of the global retail sale.

Orchid has major market opportunities in the product segments chosen. The global infectives market is valued at US$ 30 billion. Cephalosporins and combinations, betalactams and penems which constitute the field of Orchid's core competencies account for US$ 15 billion of sales. The advanced regulated markets constitute 67% of the market for anti-infectives. Specifically, the cephalosporin and betalactam product range for which Orchid has distribution alliances in the US account for a current retail market of US$ 3.25 billion. Five products which would go off patent between 2005 and 2007 and one product which is yet to be genericised in the US constitute a sale of US$ 2 billion within this space. The EU market for the products is estimated at an additional US$ 1.7 billion. In the non-penicillin, non-cephalosporins area, the 20 products that are tied up cover high growth therapeutic areas such as cardio-vascular, central nervous system, diabetes, pain management and gastro-intestinals to state a few, represent a current market value of US$ 20 billion. The larger list of such molecules identified by Orchid in such high potential therapeutic areas offers a continuous yearly market opportunity in addition.

As Orchid enters the regulated generics space with its cephalosporins from July 2005 and supplements it with other select high end anti-infective products as well as non-penicillin, non-betalactams from 2007, significant additional and attractive markets would be opened up for Orchid. With the requisite investments having been made for the cephalosporin and betalactam products as well as the first wave of non-penicillin, non-cephalosporin products, the proposed regulated market foray into the US generics space, followed by the EU generics effort would trigger significant enhancements in performance.

The growth of the generic markets has led to pressures on the global pharmaceutical corporations for increased new drug pipelines. With India recognizing product patents and enabling greater compliance with intellectual property regime, Orchid anticipates that drug discovery would offer major scope. Global pharmaceutical firms are reported to spend over US$ 55 billion per annum in R&D budgets. R&D outsourcing could therefore provide a major scientific and business opportunity for select Indian firms such as Orchid.

As in generics, Orchid has a unique end-to-end connected model in drug discovery as well. Orchid has capabilities to design drugs based on QSAR, synthesize novel pharmacophores, structures and analogues, screen them microbiologically and pharmacologically and validate the chosen hits and leads in animal models. Orchid's R&D infrastructure as well as pre-clinical facilities which can perform world-class chemistry, regulatory, toxicology and other studies are GLP accredited in line with OECD principles by India's National GLP Monitoring Authority.

Orchid has taken initiatives to develop a strong drug delivery pipeline from the in-house and Bexel programmes through greater synergy. The combined pipeline covers anti-diabetes, anti-inflammatory, anti-cancer and anti-infective therapeutic segments.

Simultaneous with the performance boosting generics and drug discovery initiatives in the advanced regulatory markets, Orchid is also consolidating and growing the base business in the less regulated and emerging markets by focusing on appropriate product-market diversification. In the overall, Orchid looks forward to exciting business opportunities and impressive performance growth.

Orchid Chemicals & Pharmaceuticals Ltd.

AUDITORS' REPORT

REPORT OF THE AUDITORS' TO THE MEMBERS

1 We have audited the attached Balance Sheet of Orchid Chemicals & Pharmaceuticals Limited (the Company) as at 31st March, 2005 and also the Profit and Loss Account of the Company for the year ended on that date annexed thereto and the Cash Flow Statement for the year ended on that date. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

2 We conducted our audit in accordance with auditing standards generally accepted in India. Those Standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

3 As required by the Companies (Auditor's Report) order 2003, issued by the Central Government of India in terms of sub-section (4A) of Section 227 of the Companies Act, 1956, we annexe hereto a statement on the matters specified in paragraphs 4 and 5 of the said Order.

4 Further to our comments in the Annexure referred to above, we report that:

a. We have obtained all the information and explanations, which to the best of our knowledge and belief were necessary for the purposes of our audit;

b. In our opinion, proper books of account as required by law have been kept by the Company so far as appears from our examination of those books;

c. The Balance Sheet, Profit and Loss Account and Cash Flow Statement dealt with by this report are in agreement with the books of account;

d. In our opinion, the Balance Sheet, Profit and Loss Account and Cash Flow Statement dealt with by this report comply with the accounting standards as referred to in sub-section (3C) of Section 211 of the Companies Act, 1956;

e. On the basis of written representations received from the directors, as on 31st March 2005, and taken on record by the Board of Directors, we report that none of the directors is disqualified as on 31st March 2005 from being appointed as a director in terms of clause (g) of sub-section (1) of Section 274 of the Companies Act, 1956;

f. In our opinion and to the best of our information and according to the explanations given to us, the said accounts give the information required by the Companies Act, 1956, in the manner so required and give a true and fair view in conformity with the accounting principles generally accepted in India:

   i. In the case of the Balance Sheet, of the state of affairs of the Company as at 31st March 2005;
   ii. In the case of the Profit and Loss Account, of the profit for the year ended on that date; and
   iii. In the case of Cash Flow Statement, of the cash flows for the year ended on that date.

For **SNB ASSOCIATES**
Chartered Accountants

(S LAKSHMANAN)
Partner
Membership No. 20045

Place: Chennai
Date : April 27, 2005

ANNEXURE TO AUDITORS' REPORT

Referred to in Paragraph 3 of our Report of even date:

1 The Company has maintained proper records showing full particulars including quantitative details and situation of its fixed assets. According to the information and explanations given to us, most of the fixed assets have been physically verified by the Management during the year. In our opinion, the frequency of such physical verification is reasonable having regard to the size of the Company and the nature of its assets. No material discrepancies were noticed on such verification as compared to the available records. There was no substantial disposal of fixed assets during the year.

2 Physical verification of Inventory has been conducted by the Management at reasonable intervals. The procedures for physical verification of stocks followed by the Management are reasonable and adequate in relation to the size of the company and nature of its business. The Company is maintaining proper records of inventory and no material discrepancies were noticed on physical verification.

3 As informed to us, the Company has granted unsecured loan to one Joint Venture company, which is covered in the register maintained under Section 301 of the Companies Act, 1956, amounting to Rs 468.22 Lakhs in terms of the Joint Venture agreement. The rate of interest and other terms and conditions of loans are as per the Joint Venture agreement, which are not prima-facie prejudicial to the interests of the company. The Company has taken reasonable steps to recover overdue interest amounting to Rs 26.87 Lakhs due from the Joint Venture Company. The Company has not taken any loans, secured or unsecured from companies, firms or other parties covered in the register maintained under Section 301 of the Companies Act, 1956.

4 In our opinion and according to the information and explanation given to us, there is adequate internal control system commensurate with the size of the Company and the nature of its business for the purchase of inventory and fixed assets and for the sale of goods and services. During the course of our audit, no major weakness has been noticed in the internal control system.

5 In our opinion and according to the information and explanation given to us, the particulars of contracts or arrangements referred to in Section 301 of the Companies Act, 1956 have been entered in the register required to be maintained under that section. The transactions made in pursuance of such contracts or arrangements have been made at prices which are reasonable having regard to the prevailing market prices / Joint venture agreements at the relevant time.

6 The Company has not accepted any deposits from the public.

7 In our opinion, the Company has an internal audit system commensurate with the size and nature of its business.

8 We have broadly reviewed the books of account maintained by the Company, pursuant to the rules made by the Central Government for the maintenance of the Cost Records under Section 209(1)(d) of the Companies Act, 1956 and are of the opinion that prima facie the prescribed accounts and records have been made and maintained.

9 The Company is regular in depositing undisputed Statutory Dues including Provident Fund, Investor Education and Protection Fund, Employees' State Insurance, Income-Tax, Sales-Tax, Wealth-Tax, Service-Tax, Custom Duty, Excise Duty, Cess and any other statutory dues applicable to it with the appropriate authorities. According to the information and explanations given to us, no undisputed amounts payable in respect of Sales-Tax, Income-Tax, Wealth Tax, Service Tax, Custom Duty, Excise Duty and Cess were outstanding at the year end for a period of more than six months from the date they became payable. According to the records of the Company, there are no disputed amounts that have not been deposited with appropriate authorities on account of Income-Tax, Sales-Tax, Wealth Tax, Service-Tax, Custom Duty, Excise Duty and Cess except the following:

Name of the Statute	Nature of the Dues	Period to which the amount relates	Amount Rs lakhs	Forum where the dispute is pending
Central Excise Act, 1944	Excise Duty	1999-00 & 2000-01	111.94	Deputy Commissioner of Central Excise, Chennai
		2000-01 & 2001-02	37.12	
		2002-03 & 2003-04	2.85	Asst. Commissioner / Superintendent of Excise & Customs, Aurangabad
		2002-03 & 2003-04	1.91	Deputy Commissioner of Excise & Customs, Aurangabad
Finance Act, 1994 (Chapter V)	Service-Tax	June 1997 to March 2001	42.26	Deputy Commissioner of Central Excise, Chennai
Tamil Nadu Tax on Consumption or sale of Electricity Act, 2003	Electricity Cess	2003-04	94.00	Honourable High Court of Chennai
		2004-05	74.31	Honourable High Court of Chennai
Income-Tax Act, 1961	Income-Tax	AY 1997-98	53.82	Income-Tax Appellate Tribunal, Chennai
Income-Tax Act, 1961	Interest on Income-Tax	AY 1997-98 & 98-99	68.88	Commissioner of Income-Tax, Chennai

Orchid Chemicals & Pharmaceuticals Ltd.

10 The Company has no accumulated losses at the end of the financial year and it has not incurred any cash losses in the current and in the immediately preceding financial year.

11 Based on our audit procedures and on the information and explanations given by the management, we are of the opinion that the Company has not defaulted in payment of dues to financial institutions and banks. The Company does not have any borrowings by way of debentures.

12 The Company has not granted any loans and advances on the basis of security by way of pledge of shares, debentures and other securities.

13 In our opinion and according to the information and explanations given to us, the nature of activities of the Company does not attract any special statute applicable to chit fund and nidhi / mutual benefit fund/societies.

14 Based on our examination of records and the information and explanations given to us, the Company has not dealt / traded in any shares, securities, debentures and other investments during the year.

15 According to the information and explanations given to us, the Company has not given any guarantee for loans taken by others from banks or financial institutions.

16 The term loans obtained by the Company were applied only for the purposes for which the loans were obtained.

17 According to the cash flow statement and other records examined by us and the information and explanations given to us on an over all basis, the funds raised on short-term basis, prima facie, have not been used during the year for long-term investment other than temporary deployment pending application except the following:

Amount (Rs lakhs)	Used for
9388.74	Fixed Assets and Investments

18 The Company has made preferential allotment of 20,00,000 warrants, to promoters covered in the register maintained under Section 301 of the Companies Act, 1956, each warrant convertible into one equity share of Rs 10 each within 18 months from the date of issue. The above issue of warrant is in accordance with SEBI guidelines.

19 The Company did not have any outstanding debentures during the year.

20 The Company has not raised any money through public issue.

21 Based on the audit procedures performed and information and explanations given by the management, we report that no fraud on or by the Company has been noticed or reported during the course of our audit.

For **SNB ASSOCIATES**
Chartered Accountants

(S LAKSHMANAN)
Partner
Membership No. 20045

Place: Chennai
Date : April 27, 2005

BALANCE SHEET AS AT MARCH 31, 2005

	SCHEDULE	AS AT 31ST MARCH 2005 Rs lakhs		AS AT 31ST MARCH 2004 Rs lakhs
I SOURCES OF FUNDS				
A SHAREHOLDERS' FUNDS				
Share Capital	A	3413.19		3238.19
Share application money pending allotment (Refer Note: 12)		24.90		–
Reserves and Surplus	B	43714.20		38631.68
B LOAN FUNDS				
Secured Loans	C	82163.11		71019.16
Unsecured Loans	D	16500.00		5000.00
C DEFERRED TAX LIABILITY (Refer Note: 24)		7416.00		7820.93
TOTAL		153231.40		125709.96
II APPLICATION OF FUNDS				
D FIXED ASSETS	E			
Gross Block		98082.47	92681.57	
Less: Depreciation		28555.46	22480.09	
Net block		69527.01	70201.48	
Capital Work in Progress		33018.61	13275.72	
Advance for capital items		1365.20	1566.13	
		103910.82		85043.33
E INVESTMENTS	F	7126.56		5230.97
F CURRENT ASSETS, LOANS AND ADVANCES				
Inventories	G	39353.57	27428.19	
Sundry Debtors	H	19780.45	15027.03	
Cash and Bank Balances	I	2027.21	2152.31	
Other Current Assets	J	54.90	37.46	
Loans and advances	K	6675.09	5464.09	
		67891.22	50109.08	
G Less: CURRENT LIABILITIES AND PROVISIONS	L	25697.20	14673.42	
		42194.02		35435.66
TOTAL		153231.40		125709.96
Notes on Accounts	R			

As per our report of even date
For **SNB ASSOCIATES**
Chartered Accountants

(S LAKSHMANAN)
Partner

Place : Chennai
Date : April 27, 2005

On behalf of the Board

R NARAYANAN
Chairman

K RAGHAVENDRA RAO
Managing Director

DR C BHAKTAVATSALA RAO
Dy Managing Director

DR J SEETHARAM NAIDU
Director

A R CHANDRASEKHARAN
President – Corporate Finance

L CHANDRASEKAR
Sr. GM – Internal Audit & Secretary

Orchid Chemicals & Pharmaceuticals Ltd.

PROFIT & LOSS ACCOUNT FOR THE YEAR ENDED MARCH 31, 2005

	SCHEDULE	FOR THE YEAR ENDED 31-03-2005 Rs lakhs		FOR THE YEAR ENDED 31-03-2004 Rs lakhs	
I INCOME					
Sales		64978.55		70008.49	
Less: Excise Duty		1138.70	63839.85	1927.09	68081.40
Other Operating Income	M	3950.89		1332.48	
Less: Excise Duty		24.04	3926.85	23.47	1309.01
Miscellaneous Income	N		82.23		123.12
			67848.93		69513.53
II EXPENDITURE					
Material Cost	O		29562.55		34967.69
Manufacturing, Selling & Other Expenses	P		21975.39		19496.74
Interest and Finance charges	Q		7231.00		6067.08
Depreciation/Amortisation			6189.19		5684.23
			64958.13		66215.74
III PROFIT					
Profit for the Year Before Tax			2890.80		3297.79
Less: Provision for Tax (Refer Note 24)					
Current Taxes		198.60		195.00	
Deferred Taxes		(404.93)	(206.33)	–	195.00
Profit for the Year After Tax			3101.13		3102.79
Balance Brought Forward			2203.99		1562.44
Balance Available for Appropriation			5305.12		4665.23
IV APPROPRIATIONS					
Transfer to General Reserve			1000.00		1000.00
Proposed Dividend		1365.28		1295.28	
Tax on Proposed Dividend		191.48	1556.76	165.96	1461.24
Balance Carried to Balance Sheet			2748.36		2203.99
V EARNINGS PER SHARE					
(Equity Shares of Rs 10/- each fully paid up)					
Basic (Rs)			9.53		9.58
Diluted (Rs)			9.05		–
Notes on Accounts	R				

As per our report of even date
For **SNB ASSOCIATES**
Chartered Accountants

(S LAKSHMANAN)
Partner

Place : Chennai
Date : April 27, 2005

On behalf of the Board

R NARAYANAN
Chairman

K RAGHAVENDRA RAO
Managing Director

DR C BHAKTAVATSALA RAO
Dy Managing Director

DR I SEETHARAM NAIDU
Director

A R CHANDRASEKHARAN
President – Corporate Finance

L CHANDRASEKAR
Sr. GM – Internal Audit & Secretary

SCHEDULES TO THE ACCOUNTS

		AS AT 31ST MARCH 2005 Rs lakhs		AS AT 31ST MARCH 2004 Rs lakhs
SCHEDULE "A" – SHARE CAPITAL				
AUTHORISED				
4,50,00,000 (Previous year 3,40,00,000) Equity Shares of Rs10/- each		4500.00		3400.00
ISSUED, SUBSCRIBED AND PAID-UP				
3,41,31,919 (Previous year 3,23,81,919) Equity Shares of Rs10/- each fully paid		3413.19		3238.19
(Of the above 17,50,000 shares of Rs10/- each at a premium of Rs 202.18 per share were allotted during the year against warrants allotted to the promoter group)				
SCHEDULE "B" – RESERVES & SURPLUS				
Securities Premium Account				
– Opening Balance	31336.20		31336.20	
– Additions during the year	3538.15	34874.35	–	31336.20
General Reserve				
– Opening Balance	5091.49		4091.49	
– Add: Transfers during the year	1000.00	6091.49	1000.00	5091.49
Surplus in Profit & Loss Account		2748.36		2203.99
		43714.20		38631.68
SCHEDULE "C" – SECURED LOANS				
From Banks				
– Rupee Term Loans	31913.72		17078.15	
– Foreign Currency Term Loans	19180.36		13239.38	
– Rupee & Foreign Currency Working Capital Loans	3881.84		4890.45	
– Rupee & Foreign Currency Packing Credit & Advance against Bills	24424.27		23724.02	
		79400.21		58932.00
From Financial Institutions				
Rupee				
– Term Loans	5406.25		6093.75	
– Working Capital Loans	5000.00		1875.00	
Foreign Currency				
– Term Loans	1251.55		1716.56	
– Working Capital Loans		11657.80	2311.92	11997.23
Hire Purchase Finance		105.10		89.93
		91163.11		71019.16

Rupee Term Loan from HDFC Ltd amounting to Rs 2125.00 lakhs is secured by charge on the corporate office building at Chennai. Term loan from Bank of Baroda for NPNC project is secured on the assets of NPNC project at Aurangabad and Irungattukottai. All other Rupee Term Loans and Foreign Currency Term Loans from Banks & Financial Institutions are secured by Pari Passu charge by way of joint mortgage on immovable and movable assets situated at Factory premises at SIDCO Industrial Area, Alathur, MIDC Industrial Area, Aurangabad, SIPCOT Industrial Park, Irungattukottai and R&D premises at Sholinganallur and current assets, subject to prior charges created/ to be created on current assets in favour of bankers and financial institutions for securing working capital borrowings. Total term loans aggregating Rs 9822.17 lakhs are additionally secured by personal guarantees of Shri K Raghavendra Rao, Managing Director of the Company.

Packing Credit and Advances against bills from Banks and Working Capital Loans from Banks and financial institutions are secured by first charge on all current assets namely, Stocks of Raw materials, Semi-finished & Finished Goods, Stores and Spares not relating to Plant & Machinery (Consumable Stores and Spares), Bills Receivable, Book Debts & all other movable property both present and future excluding such movables as may be permitted by the banks/financial institutions from time to time and by second charge on immovable properties other charges created/ to be created on immovable assets in favour of Financial Institutions/Banks for securing Term Loans. The borrowings from banks are additionally secured by personal guarantee of Shri K Raghavendra Rao, Managing Director of the Company.

Hire purchase Loans are secured by the assets acquired through such loans

SCHEDULE "D" – UNSECURED LOANS			
From Banks	16500.00		5000.00
	16500.00		5000.00

SCHEDULES TO THE ACCOUNTS

SCHEDULE "E" – FIXED ASSETS

Rs lakhs

Sl No	ASSET DESCRIPTION	GROSS BLOCK (AT COST)				DEPRECIATION/AMORTISATION				WRITTEN DOWN VALUE	
		AS AT 01-Apr-04	ADDITIONS DURING THE YEAR	DELETIONS DURING THE YEAR	AS AT 31-Mar-05	UP TO 31-Mar-04	FOR THE YEAR	ON DELETIONS	UP TO 31-Mar-05	AS AT 31-Mar-05	AS AT 31-Mar-04
1	FREEHOLD LAND & SITE DEVELOPMENT	1100.52	2.77	11.90	1091.39	–	–	–	–	1091.39	1100.52
2	LEASEHOLD LAND	636.86	6.19	–	643.05	–	–	–	–	643.05	636.86
3	BUILDINGS	9425.40	367.41	30.55	9762.26	1062.03	306.88	1.91	1367.00	8395.26	8363.37
4	PLANT & MACHINERY	70620.21	3475.11	60.78	74034.54	19182.46	4881.71	48.33	24015.84	50018.70	51437.75
5	FACTORY EQUIPMENT	684.84	48.84	–	733.68	260.25	73.59	–	333.84	399.84	424.59
6	LABORATORY EQUIPMENT	4317.53	543.21	139.60	4721.14	571.09	227.36	7.18	791.27	3929.87	3746.44
7	OFFICE EQUIPMENT	1480.18	50.25	28.25	1502.18	495.80	154.21	24.17	625.84	876.34	984.38
8	FURNITURE & FITTINGS	983.74	87.68	14.02	1057.40	244.69	61.53	4.14	302.08	755.32	739.05
9	VEHICLES	460.32	141.57	109.04	492.85	113.77	43.91	28.09	129.59	363.26	346.55
10	INTANGIBLE ASSETS										
	ACQUIRED BRANDS & TRADEMARKS *	2200.00	–	–	2200.00	550.00	440.00	–	990.00	1210.00	1650.00
	INTERNALLY GENERATED DMF & ANDA **	771.97	1072.01	–	1843.98	–	–	–	–	1843.98	771.97
	TOTAL	92681.57	5795.04	394.14	98082.47	22480.09	6189.19	113.82	28555.46	69527.01	70201.48
	PREVIOUS YEAR'S FIGURES	78063.10	14927.60	309.13	92681.57	16866.99	5684.23	71.13	22480.09	70201.48	

* Represents value of applications filed pending registration

** Refer Note 1 (b) (iv) of Schedule R

Orchid Chemicals & Pharmaceuticals Ltd.

OCP0000400

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SCHEDULES TO THE ACCOUNTS

	Nos	AS AT 31ST MARCH 2005 Rs lakhs	Nos	AS AT 31ST MARCH 2004 Rs lakhs
SCHEDULE "F" – INVESTMENTS				
(at cost)				
LONG TERM				
Trade, UnQuoted				
Subsidiary Companies				
Orchid Europe Limited, UK (previously known as Orchid Nutricare Limited)				
Common stock of GBP 1 each fully paid-up	10000	6.42	10000	6.42
Less: Provision for diminution in value		(6.42)		(6.42)
		–		–
Ogna Farma, Brazil				
Common stock		54.07		25.73
Gene Arrays Inc., USA*				
Preferred stock with par value of US$ 0.001	200000	91.10		–
Orchid Pharmaceuticals Inc., USA				
Common stock of US$ 1 each fully paid-up	100	0.04		–
		145.21		25.73
Joint Venture Companies				
BChD Biotechnological Chemical Development Limited, UK				
Common stock of GBP 1 each fully paid-up	31100	21.03	31100	21.03
NCPC Orchid Pharmaceuticals Company Ltd, China		2364.24		2364.24
Common stock representing 50% interest in the company				
Bexel Pharmaceutical Inc.**				
9,999,990 Series A Convertible Preferred Stock par value USD 0.001 per share and 10 Common stock of par value USD 0.001 per share	10000000	4585.71	6060000	2811.60
		6970.98		5196.87
Others:				
Orchid Research Laboratories Ltd.				
Fully paid-up equity shares of Rs 10/- each	20000	2.00	–	–
Non – Trade, Quoted				
Bank of India –				
Fully paid-up Equity shares of Rs 10/- each	18600	8.37	18600	8.37
		8.37		8.37
Total Value of Investments		7126.56		5230.97

Market Value for quoted investment is Rs 19.27 Lakhs (Previous year Rs 10.89 Lakhs)

Units bought and sold during the year
- Chola Triple Ace - 80631800.92 units valued at Rs 8197.47 Lakhs
- Reliance – Liquid Fund - 13102222.32 units valued at Rs 2001.57 Lakhs
- Kotak Mahindra – Liquid Fund - 24556893.59 units valued at Rs 3002.84 Lakhs
- Standard Chartered – Liquid Fund -17574000.78 units valued at Rs 1801.39 Lakhs

* Each Preferred stock is convertible into One Common stock, at any time, at the option of the Company and will have voting rights equal to one common stock and has the same value as common stock.

** Each Series A Preferred stock is convertible into One Common stock, at any time, at the option of the Company and will have voting rights equal to one common stock and has the same value as common stock.

Orchid Chemicals & Pharmaceuticals Ltd.

SCHEDULES TO THE ACCOUNTS

	AS AT 31ST MARCH 2005 Rs lakhs	AS AT 31ST MARCH 2004 Rs lakhs
SCHEDULE "G" – INVENTORIES (Refer Note 1 (f), Schedule "R")		
Raw materials	8088.49	6026.47
Stores and Spare parts	1288.40	1246.99
Chemicals and Consumables	518.19	438.54
Packing Materials	552.32	366.06
Intermediates & WIP	23692.65	15485.87
Finished Goods	4482.16	2850.99
Traded Goods	756.36	1013.27
	39378.57	27428.19
SCHEDULE "H" – SUNDRY DEBTORS		
Debts more than 6 months (Unsecured)		
– Considered Good	18692.41	12478.86
– Considered Doubtful	1615.11	1435.11
Other Debts (Considered Good)		
– Secured	81.43	6.72
– Unsecured	3006.61	2541.45
	21395.56	16462.14
Less: Provision for Doubtful Debts	1615.11	1435.11
	19780.45	15027.03
SCHEDULE "I" – CASH AND BANK BALANCES		
CASH IN HAND	10.59	22.92
Balances with Scheduled Banks on:		
– Current Account	718.82	800.44
– Term Deposit Account	0.50	80.11
– Margin Money Deposit	1249.19	1201.36
– Share Application Money and Dividend Account	58.11	47.48
	2037.21	2152.31
SCHEDULE "J" – OTHER CURRENT ASSETS		
Interest Accrued on Deposits and Advances*	25.97	58.53
Less: Provision for Doubtful Advances	21.07	21.07
*Includes dues from subsidiary Rs 21.07 lakhs (Previous Year Rs 21.07 lakhs)	4.90	37.46
SCHEDULE "K" – LOANS AND ADVANCES (UNSECURED)		
Considered Good		
Share Application Money Pending Allotment	–	4.39
Advances recoverable in cash or kind or for value to be received*	5703.62	4680.87
Advance Payment of Tax	730.86	491.25
Loans to Subsidiaries	3.74	–

SCHEDULES TO THE ACCOUNTS

	AS AT 31ST MARCH 2005 Rs lakhs	AS AT 31ST MARCH 2004 Rs lakhs
Deposits		
– With Government Authorities	162.72	219.13
– Others	69.15	68.45
Considered Doubtful		

EXHIBIT 7

FULLY REDACTED

EXHIBIT 8

FULLY REDACTED

EXHIBIT 9

FULLY REDACTED

EXHIBIT 10

FULLY REDACTED

EXHIBIT 11

FULLY REDACTED

EXHIBIT 12

FULLY REDACTED

EXHIBIT 13

FULLY REDACTED

EXHIBIT 14

FULLY REDACTED

EXHIBIT 15

FULLY REDACTED

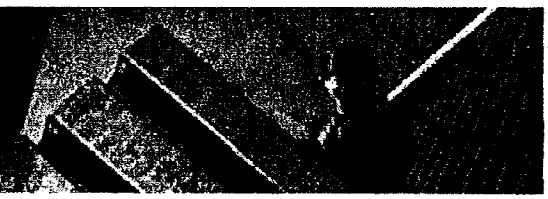
EXHIBIT 16

FULLY REDACTED

EXHIBIT 17

Select Industry
- Select -
»

DuPont Consulting Services



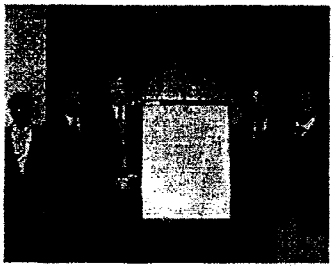
Top Pharmaceutical Company Signs World Safety Declaration

Wilmington, Delaware, January 18, 2008

Orchid Chemicals & Pharmaceuticals, one of India's top pharmaceutical companies, recently signed the World Safety Declaration. Orchid became the 47th charter signer, joining leaders across industries throughout the world who are dedicated to improving safety in the workplace.

WorldSafety DECLARATION

Signers of the World Safety Declaration have made a public commitment to report their challenges, progress and successes at the 18th World Congress on Safety and Health at Work in Seoul, Korea, in 2008. The World Safety Declaration was initiated by DuPont at the last World Congress in 2005.



"We are embarking on this journey with great commitment," said K. Raghavendra Rao, Managing Director. "We believe we can achieve more through collaboration - and what better safety partner than DuPont?"

"Orchid is both a fast growing leader in the Indian pharmaceutical industry and a leader in safety," said Jim Weigand – vice president and general manager of DuPont Safety Resources. "Since its inception 14 years ago, Orchid has made safety a core value that is closely linked to business success. We are honored that they have joined this important effort."

To see other World Safety Declaration signers and learn more, please click here.

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EXHIBIT 18

FULLY REDACTED

EXHIBIT 19

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
FILED 09:00 AM 05/23/2000
001261266 - 3232982

CERTIFICATE OF FORMATION

OF

CHEVRON PHILLIPS CHEMICAL COMPANY LLC

The undersigned authorized person hereby certifies as follows:

1. The name of the limited liability company is Chevron Phillips Chemical Company LLC.

2. The address of its registered office in the State of Delaware is 1013 Centre Road in the City of Wilmington, County of New Castle. The name of its registered agent at such address is Corporation Services Company.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Formation on this 23rd day of May, 2000.

G. W. Lee
Authorized Person

CONSENT TO USE OF NAME

Chevron Phillips Chemical Company LP, a limited partnership organized under the laws of the State of Delaware, hereby consents to the organization of Chevron Phillips Chemical Company LLC in the State of Delaware.

IN WITNESS WHEREOF, the said Chevron Phillips Chemical Company LP, has caused this consent to be executed by its Senior Vice President, as appointed by the General Partner, on this 23rd day of May 2000.

Chevron Phillips Chemical Company LP

By _____
Greg C. Garland
Senior Vice President

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
FILED 05:00 PM 11/14/2002
020704282 – 3232982

CERTIFICATE OF AMENDMENT

OF

CHEVRON PHILLIPS CHEMICAL COMPANY LLC

1. The name of the limited liability company is Chevron Phillips Chemical Company LLC.

2. The Certificate of Formation of the limited liability company is hereby amended as follows:

The address of its registered office in the State of Delaware is Corporation Trust Center, 1209 Orange Street, in the City of Wilmington, County of New Castle. The name of its registered agent at such address is The Corporation Trust Company.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Amendment of Chevron Phillips Chemical Company LLC this 5 day of November, 2002.

Lisa M. Lynch, Authorized Person

DE084 - 2/12/2002 C T System Online

EXHIBIT 20

CERTIFICATE OF INCORPORATION

OF

DRG MEDICAL PACKAGING, INC.

8610-34

FILED

OCT 5 1978 10 AM

SECRETARY OF STATE

00001

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CERTIFICATE OF INCORPORATION

OF

DRG MEDICAL PACKAGING, INC.

1. The name of the corporation is DRG MEDICAL PACKAGING, INC.

2. The address of its registered office in the State of Delaware is No. 100 West Tenth Street, in the City of Wilmington, County of New Castle. The name of its registered agent at such address is The Corporation Trust Company.

3. The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware.

4. The total number of shares of stock which the corporation shall have authority to issue is One Thousand (1,000) and the par value of each of such shares is One Dollar ($1.00) amounting in the aggregate to One Thousand Dollars ($1,000.00).

5. The name and mailing address of each incorporator is as follows:

NAME	MAILING ADDRESS
M. A. Ferrucci	100 West Tenth Street Wilmington, Delaware 19801
F.J. Obara, Jr.	100 West Tenth Street Wilmington, Delaware 19801
W. J. Reif	100 West Tenth Street Wilmington, Delaware 19801

6. The corporation is to have perpetual existence.

00002

7. In furtherance and not in limitation of the powers conferred by statute, the board of directors is expressly authorized to make, alter or repeal the by-laws of the Corporation.

8. Elections of directors need not be by written ballot unless the by-laws of the corporation shall so provide.

Meetings of stockholders may be held within or without the State of Delaware, as the by-laws may provide. The books of the corporation may be kept (subject to any provision contained in the statutes) outside the State of Delaware at such place or places as may be designated from time to time by the board of directors or in the by-laws of the corporation.

9. The corporation reserves the right to amend, alter, change or repeal any provision contained in the certificate of incorporation, in the manner now or hereafter prescribed by statute, and all rights conferred upon stockholders herein are granted subject to this reservation.

WE, THE UNDERSIGNED, being each of the incorporators hereinbefore named, for the purpose of forming a corporation pursuant to the General Corporation Law of the State of Delaware, do make this certificate, hereby declaring and certifying that this is our act and deed and the facts herein stated are true, and accordingly have hereunto set our hands this 5th day of October, 1978.

M. A. Ferrucci

P. J. Cobra, Jr.

W. J. Reif

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3740S
01/27/82

CERTIFICATE OF OWNERSHIP AND MERGER

MERGING

FORDEM COMPANY

INTO

DRG MEDICAL PACKAGING, INC.

FILED

FEB 2 1982 12:3

SECRETARY OF STATE

* * * * *

DRG MEDICAL PACKAGING, INC., a corporation organized and existing under the laws of the State of Delaware,

DOES HEREBY CERTIFY:

FIRST: That this corporation was incorporated on October 5, 1978, pursuant to the General Corporation Law of the State of Delaware.

SECOND: That this corporation owns all of the outstanding shares of capital stock of Fordem Company, which was incorporated on August 24, 1944 pursuant to the Business Corporation Law of the State of Wisconsin, the provisions of which permit the merger of a corporation of the State of Wisconsin into a corporation organized and existing under the laws of another state.

THIRD: That the following resolutions providing for the merger of Fordem Company into DRG MEDICAL PACKAGING, INC. were duly adopted by the unanimous written consent of the Board of Directors of DRG MEDICAL PACKAGING, INC. on February 2, 1982.

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RESOLVED, that pursuant to Section 253 of the General Corporation Law of the State of Delaware this Corporation merge, and it does hereby merge, its wholly-owned subsidiary, Fordem Company, a Wisconsin corporation, into itself pursuant to the Plan of Merger attached hereto as Exhibit A, which is hereby approved.

RESOLVED, that the proper officers of this Corporation be and they hereby are directed to make and execute a Certificate of Ownership and Merger setting forth a copy of the foregoing resolution and the date of adoption thereof, and to cause the same to be filed with the Secretary of State of the State of Delaware and a certified copy thereof to be recorded in the office of the Recorder of Deeds of New Castle County, Delaware and to execute, and join in filing with the Secretary of State of the State of Wisconsin, Articles of Merger and to do all acts and things whatsoever, whether within or without the State of Delaware, which may be in anywise necessary or proper to effect said merger.

FOURTH: The Plan of Merger referred to in the preceding resolutions is attached hereto as Exhibit A.

FIFTH: The Surviving Corporation shall be DRG MEDICAL PACKAGING, INC.

IN WITNESS WHEREOF, DRG MEDICAL PACKAGING, INC. has caused this certificate to be signed by Dr. Richard J. M. Hobbs, its President, and attested by Charles I. Thompson, Jr., its Secretary, as of the 2nd day of February, 1982.

DRG MEDICAL PACKAGING, INC.

By: Richard J. M. Hobbs
Dr. Richard J. M. Hobbs

DRG MEDICAL PACKAGING, INC. CORPORATE SEAL DELAWARE 1982 Attest

Charles I. Thompson, Jr.

00006

3736S
01/27/82

EXHIBIT A

PLAN OF MERGER

1. Fordem Company, a Wisconsin corporation, shall be merged into DRG MEDICAL PACKAGING, INC., a Delaware corporation, which shall survive the merger.

2. The merger shall become effective upon the last to occur of (a) the filing of the Articles of Merger with respect thereto with the Secretary of State of the State of Wisconsin, (b) the filing of the Certificate of Ownership and Merger with respect thereto with the Secretary of State of the State of Delaware and (c) the close of business on February 2, 1982 (the "Effective Date").

3. DRG MEDICAL PACKAGING, INC. as the surviving corporation (herein as such called the "Surviving Corporation") shall continue its corporate existence under the laws of the State of Delaware.

4. The name of the Surviving Corporation shall be "DRG MEDICAL PACKAGING, INC."

5. The directors of DRG MEDICAL PACKAGING, INC. shall continue as the directors of the Surviving Corporation until their successors are elected and qualified.

6. On the Effective Date, the separate existence of Fordem Company, a Wisconsin corporation, shall cease.

7. The Certificate of Incorporation of DRG MEDICAL PACKAGING, INC. shall be the Certificate of Incorporation of the Surviving Corporation until altered, amended or repealed in accordance with the provisions thereof and of applicable law.

8. The By-Laws of DRG MEDICAL PACKAGING, INC. shall be the By-Laws of the Surviving Corporation until altered, amended or repealed in accordance with the provisions thereof, of the Certificate of Incorporation and of applicable law.

9. On the Effective Date, each share of capital stock of Fordem Company issued immediately prior to the Effective Date, including shares held in its treasury, shall, by virtue of the merger and without any action on the part of the holder thereof, cease to exist and be cancelled.

10. On the Effective Date, each share of stock of DRG MEDICAL PACKAGING, INC. issued immediately prior to the Effective Date shall continue to be one issued share of stock of the Surviving Corporation.

Certificate of Ownership of the "DRG MEDICAL PACKAGING, INC.",
a corporation organized and existing under the laws of the State of Delaware,
merging "FORDEM COMPANY",
a corporation organized and existing under the laws of the State of Wisconsin,
pursuant to Section 253 of the General Corporation Law of the State of Delaware,
as received and filed in this office the second day of February,
A.D. 1982, at 12:30 o'clock P. M.

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
FILED 09:00 AM 07/10/1992
921955359 - 861034

CERTIFICATE OF CHANGE OF LOCATION OF REGISTERED OFFICE

AND OF REGISTERED AGENT

It is hereby certified that:

1. The name of the corporation (hereinafter called the "corporation") is: DRG MEDICAL PACKAGING, INC.

2. The registered office of the corporation within the State of Delaware is hereby changed to 32 Loockerman Square, Suite L-100, Dover, Delaware 19901, County of Kent.

3. The registered agent of the corporation within the State of Delaware is hereby changed to The Prentice-Hall Corporation System, Inc., the business office of which is identical with the registered office of the corporation as hereby changed.

4. The corporation has authorized the changes hereinbefore set forth by resolution of its Board of Directors.

Signed on July 2, 1992.

Ronald H. Lassiter
(Vice) President

Attest:

Peggy B. Flannigan
(Assistant) Secretary

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
FILED 09:00 AM 12/30/1994
944260929 - 861034

CERTIFICATE OF OWNERSHIP AND MERGER
of
DRG, INCORPORATED
into
DRG MEDICAL PACKAGING, INC.

It is hereby certified that:

1. DRG, Incorporated (the "Corporation") is a corporation of the State of Delaware.

2. The Corporation, as the owner of all of the outstanding shares of common stock of DRG Medical Packaging, Inc., hereby merges itself into DRG Medical Packaging, Inc., a corporation of the State of Delaware which shall survive.

3. The following is a copy of the resolutions adopted on the 21st day of December, 1994, by the Board of Directors of the Corporation to merge the Corporation into DRG Medical Packaging, Inc.:

RESOLVED that this Corporation be merged with DRG Medical Packaging, Inc. pursuant to the laws of the State of Delaware as hereinafter provided, which shall survive, so that the separate existence of this Corporation shall cease as soon as the merger shall become effective on December 30, 1994, and thereupon this Corporation and DRG Medical Packaging, Inc. will become a single corporation, which shall continue to exist under, and be governed by, the laws of the State of Delaware.

RESOLVED that the terms and conditions of the proposed merger are as follows:

(a) From and after December 30, 1994, the effective time of the merger, all of the estate, property, rights, privileges, powers and franchises of this Corporation shall become vested in and be held by DRG Medical Packaging, Inc. as fully and entirely and without change or diminution as the same were before held and enjoyed by this Corporation, and DRG Medical Packaging, Inc. shall assume all of the obligations of this Corporation.

(b) No pro rata issuance of the shares of stock of DRG Medical Packaging, Inc. which are owned by this Corporation immediately prior to the effective time of the merger shall be made, and such shares shall be extinguished.

(c) Each share of common stock, $1.00 par value, of this Corporation which shall be issued and outstanding immediately prior to the effective time of the merger shall be converted into one issued and outstanding share of common stock, $1.00 par value of DRG Medical Packaging, Inc., and, from and after the effective time of the merger, the holders of all of said issued and outstanding shares of common stock of this Corporation shall automatically be and become holders of

shares of DRG Medical Packaging, Inc. upon the basis above specified, whether or not certificates representing said shares are then issued and delivered.

(d) After the effective time of the merger, the holder of record of all outstanding certificates therefore representing common stock of this Corporation may surrender the same to DRG Medical Packaging, Inc. at its registered office and such holder shall be entitled upon such surrender to receive in exchange therefor certificates representing an equal number of shares of common stock of DRG Medical Packaging, Inc. Until so surrendered, each outstanding certificate which prior to the effective time of the merger presented one or more shares of common stock of this Corporation shall be deemed for all corporate purposes to evidence ownership of an equal number of shares of common stock of DRG Medical Packaging, Inc.

(e) From and after December 30, 1994, the effective time of merger, the Certificate of Incorporation and the By-Laws of DRG Medical Packaging, Inc. shall be the Certificate of Incorporation and By-Laws of DRG Medical Packaging, Inc. as in effect immediately prior to such effective time and said Certificate of Incorporation shall continue in full force and effect until amended and changed in the manner prescribed by the provisions of the General Corporation Law of the State of Delaware.

(f) The members of the Board of Directors and officers of DRG Medical Packaging, Inc. immediately before the effective time of the merger shall be the members of the Board of Directors and the corresponding officers of DRG Medical Packaging, Inc. after the merger.

(g) From and after the effective time of the merger, the assets and liabilities of this Corporation and of DRG Medical Packaging, Inc. shall be entered on the books of DRG Medical Packaging, Inc. at the amounts of which they shall be carried at such time on the respective books of this Corporation and of DRG Medical Packaging, Inc., subject to such inter-corporate adjustments or eliminations, if any, as may be required to give effect to the merger; and, subject to such action as may be taken by the Board of Directors of DRG Medical Packaging, Inc., in accordance with generally accepted accounting principles, the capital and surplus of DRG Medical Packaging, Inc. shall be the capital and surplus of DRG Medical Packaging, Inc. after the merger.

4. The proposed merger therein certified has been approved in writing by the holder of all of the outstanding stock of the Corporation in accordance with the provisions of Section 228 of the General Corporation Law of the State of Delaware.

The effective time of this Certificate of Ownership and Merger, and the time when the merger therein certified shall become **effective**, shall be **December 30, 1994**.

Signed on December 21, 1994.

DRG, INCORPORATED

By: _____
Vice President

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
FILED 10:46 AM 06/01/1995
950120944 - 861034

CERTIFICATE OF AMENDMENT
OF CERTIFICATE OF INCORPORATION
OF
DRG MEDICAL PACKAGING, INC.

It is certified that:

1. The name of the corporation is DRG Medical Packaging, Inc (the "Corporation").

2. The Certificate of Incorporation of the Corporation is hereby amended by striking out the FIRST Article thereof and by substituting in lieu of said Article the following new Article:

FIRST: The name of the Corporation is

Rexam Medical Packaging Inc.

3. The amendment of the Certificate of Incorporation herein certified has been duly adopted in accordance with the provisions of Section 228 and 242 of the General Corporation Law of the State of Delaware.

4. The effective date of the amendment shall be June 1, 1995.

5. The foregoing amendment of the Certificate of Incorporation of the Corporation was authorized by the consent in writing of all the members of the Board of Directors of the Corporation, followed by the unanimous written consent of the holder of all of the outstanding shares of the Corporation entitled to vote on the said amendment of the Certificate of Amendment.

Signed and attested this 31st day of May, 1995.

Frank C. Brown, Director
and Vice President

ATTEST:

Gerald F. Moran
Assistant Secretary

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
FILED 09:00 AM 05/29/1996
960155319 - 861034

CERTIFICATE OF CHANGE OF LOCATION OF REGISTERED OFFICE AND OF REGISTERED AGENT

It is hereby certified that:

1. The name of the corporation (hereinafter called the "corporation") is REXAM MEDICAL PACKAGING INC.

2. The registered office of the corporation within the State of Delaware is hereby changed to 9 East Loockerman Street, City of Dover 19901, County of Kent.

3. The registered agent of the corporation within the State of Delaware is hereby changed to National Registered Agents, Inc., the business office of which is identical with the registered office of the corporation as hereby changed.

4. The corporation has authorized the changes hereinbefore set forth by resolution of its Board of Directors.

Signed on: May 10, 1996

Peggy Harrington

Peggy Harrington, Assistant Secretary

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
FILED 09:00 AM 12/22/1997
971440978 – 0861034

CERTIFICATE OF OWNERSHIP AND MERGER
OF
REXAM MEDICAL PACKAGING-MPI INC.
(a Delaware corporation)
into
REXAM MEDICAL PACKAGING INC.
(a Delaware corporation)

Rexam Medical Packaging Inc. (hereinafter called the "Corporation"), a corporation organized and existing under and by virtue of the Delaware General Corporation Law, does hereby certify:

1. Rexam Medical Packaging Inc. is a business corporation of the State of Delaware.

2. The Corporation is the owner of all of the outstanding shares of stock of Rexam Medical Packaging-MPI Inc., which is also business corporation of the State of Delaware.

3. The laws of jurisdiction of organization of Rexam Converting Inc. permit the merger of a business corporation of that jurisdiction with a business corporation of another jurisdiction.

4. On December 19, 1997, the Board of Directors of the Corporation adopted the following resolutions to merge Rexam Medical Packaging-MPI Inc. into the Corporation:

RESOLVED that Rexam Medical Packaging-MPI Inc. be merged into this Corporation, and that all of the estate, property, rights, privileges, powers, and franchises of Rexam Medical Packaging-MPI Inc. be vested in and held and enjoyed by this Corporation as fully and entirely and without change or diminution as the same were before held and enjoyed by Rexam Medical Packaging-MPI Inc. in its name.

RESOLVED that the effective date of the merger is December 31, 1997 in Delaware.

RESOLVED, that this Corporation assume all of the obligations of Rexam Converting Inc.

RESOLVED that this Corporation shall cause to be executed and filed and/or recorded the documents prescribed by the laws of the State of Delaware, and by the laws of any other appropriate jurisdiction and will cause to be performed all necessary acts within the State of Delaware and in any other appropriate jurisdiction.

Executed on this 19th day of December, 1997.

REXAM MEDICAL PACKAGING INC.

By: _____
Vice President and Secretary

CERTIFICATE OF MERGER

OF

REXAM PLASTICS INC.

AND

REXAM MEDICAL PACKAGING INC.

It is hereby certified that:

1. The constituent business corporations participating in the merger herein certified are:

(i) **Rexam Plastics Inc.**, which is incorporated under the laws of the State of Indiana; and

(ii) **Rexam Medical Packaging Inc.**, which is incorporated under the laws of the State of Delaware; and

2. An Agreement of Merger has been approved, adopted, certified, executed, and acknowledged by each of the aforesaid constituent corporations in accordance with the provisions of subsection (c) of Section 252 of the Delaware General Corporation Law, to wit, by Rexam Plastics Inc. in accordance with the laws of the State of its incorporation and by Rexam Medical Packaging Inc. in the same manner as is provided in Section 251 of the Delaware General Corporation Law.

3. The name of the surviving corporation in the merger herein certified is **Rexam Medical Packaging Inc.**, which will continue its existence as said surviving corporation under its present name upon the effective date of said merger pursuant to the provisions of the Delaware General Corporation Law.

4. The Certificate of Incorporation of **Rexam Medical Packaging Inc.**, as now in force and effect, shall continue to be the Certificate of Incorporation of said surviving corporation until amended and changed pursuant to the provisions of the Delaware General Corporation Law.

5. The executed copy of the Agreement of Merger between the aforesaid constituent corporations is on file at the principal place of business of the aforesaid surviving corporation, the address of which is as follows:

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
FILED 11:00 AM 12/28/1998
981502075 – 0861034

Rexam Medical Packaging Inc.
Suite 340
4201 Congress Street
Charlotte, NC 28209

6. A copy of the aforesaid Agreement of Merger will be furnished by the aforesaid surviving corporation, on request, and without cost, to any shareholder of each of the aforesaid constituent corporations.

7 The authorized capital stock of Rexam Plastics Inc. consists of 5,000 shares of a par value of $100.00.

8. The effective date of the merger is December 31, 1998.

Executed this 28th day of December, 1998.

REXAM MEDICAL PACKAGING INC.

By: _____
Vice President and Secretary
Frank C. Brown

CERTIFICATE OF AMENDMENT OF CERTIFICATE OF INCORPORATION
OF

REXAM MEDICAL PACKAGING INC.

REXAM MEDICAL PACKAGING INC. (hereinafter called the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware, does hereby certify:

1 The name of the corporation is REXAM MEDICAL PACKAGING INC.

2. The Certificate of Incorporation of the Corporation is hereby amended by striking out the FIRST Article thereof and by substituting in lieu of said FIRST Article the following new Article:

FIRST: The name of the corporation is **REXAM HEALTHCARE FLEXIBLES INC.**

3. The amendment of the Certificate of Incorporation herein certified has been duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

4. The effective date of the amendment shall be with the filing of this Amendment of the Certificate of Incorporation.

5. The foregoing amendment of the Certificate of Incorporation of the Corporation was authorized by the consent in writing of all the members of the Board of Directors of the Corporation, followed by the unanimous written consent of the holder of all of the outstanding shares of the Corporation entitled to vote on the said amendment of the Certificate of Amendment.

Signed and attested on this 25th day of March, 2003.

Frank C. Brown
Director, Vice President & Secretary

ATTEST:

Assistant Secretary

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
FILED 01:58 PM 03/25/2003
030197962 – 0861034

State of Delaware
Secretary of State
Division of Corporations
Delivered 04:51 PM 10/20/2003
FILED 04:46 PM 10/20/2003
SRV 030672832 - 0861034 FILE

CERTIFICATE OF AMENDMENT OF CERTIFICATE OF INCORPORATION

OF

REXAM HEALTHCARE FLEXIBLES INC.

Rexam Healthcare Flexibles Inc. (hereinafter called the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware, does hereby certify:

1. The name of the corporation is Rexam Healthcare Flexibles Inc.

2. The Certificate of Incorporation of the Corporation is hereby amended by striking out the FIRST Article thereof and by substituting in lieu of said Article the following new Article:

FIRST: The name of the Corporation is **REXAM CLOSURES AND CONTAINERS INC.**

3. The amendment of the Certificate of Incorporation herein certified has been duly adopted in accordance with the provisions of Sections 228 and 242 of the General Corporation Law of the State of Delaware.

4. The foregoing amendment of the Certificate of Incorporation of the Corporation was authorized by the consent in writing of all the members of the Board of Directors of the Corporation, followed by the unanimous written consent of the sole shareholder of the Corporation.

Executed on this 13th day of October, 2003.

Frank C. Brown, Vice President

EXHIBIT 21

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
FILED 09:30 AM 06/10/2002
020370010 – 3527938

RESTATED CERTIFICATE OF INCORPORATION
OF
SELIG HOLDINGS CORPORATION

Selig Holdings Corporation, a corporation organized and existing under the laws of the State of Delaware, hereby certifies as follows:

1. The name of the Corporation is Selig Holdings Corporation. The date of filing its original Certificate of Incorporation with the Secretary of State was May 21, 2002.

2. This Restated Certificate of Incorporation restates and integrates and further amends the Certificate of Incorporation by amending Article Fourth to increase the number of shares from 1,000 shares to 200,000 shares and adding Articles Ninth and Tenth.

3. The text of the Certificate of Incorporation as amended or supplemented heretofore is further amended hereby to read as herein set forth in full:

FIRST. The name of the Corporation is Selig Holdings Corporation.

SECOND. The Corporation's registered office in the State of Delaware is located at Corporation Trust Center, 1209 Orange Street in the City of Wilmington, County of New Castle. The name of its registered agent at such address is The Corporation Trust Company.

THIRD. The purpose of the corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware.

FOURTH. The total number of shares of capital stock which the Corporation shall have authority to issue is two hundred thousand (200,000) shares of Common Stock, with a par value of one cent ($.01) per share.

FIFTH. The name and mailing address of the incorporator is as follows:

Béla R. Schwartz
The Riverside Company
630 Fifth Avenue, Suite 1530
New York, NY 10111

SIXTH. The powers of the incorporator shall cease upon the filing of this certificate with the Secretary of State of the State of Delaware, and the following persons shall serve as the directors of the Corporation until the first annual meeting of stockholders or until their successors are elected and qualify:

Robert J. Fitzsimmons
The Riverside Company
630 Fifth Avenue, Suite 1530
New York, NY 10111

Anne D. Farrar
The Riverside Company
455 Market St., Suite 1520
San Francisco, CA 94105

SEVENTH. Meetings of stockholders may be held outside the State of Delaware, if the Bylaws of the Corporation so provide. The books of the Corporation may be kept (subject to any provision contained in the statutes) outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the Corporation. Elections of directors need not be by ballot, unless the Bylaws of the Corporation shall so provide.

EIGHTH. The management of the business and the conduct of the affairs of the corporation shall be vested in its Board of Directors. The number of directors which shall constitute the whole Board of Directors shall be fixed in the manner provided in the Bylaws of the corporation.

NINTH. Each person who is or was or had agreed to become a director or officer of the Corporation, or each person who is or was serving or who had agreed to serve at the request of the Board of Directors or an officer of the Corporation as an employee or agent of the Corporation or as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise (including the heirs, executors, administrators or estate of such person), shall be indemnified by the Corporation to the full extent permitted by the General Corporation Law of the State of Delaware or any other applicable laws as presently or hereafter in effect. Without limiting the generality or the effect of the foregoing, the Corporation may enter into one or more agreements with any person which provide for indemnification greater or different that that provided in this Article. Any repeal or modification of this Article Ninth shall not adversely affect any right or protection existing hereunder immediately prior to such repeal or modification.

TENTH. In furtherance and not in limitation of the rights, powers, privileges, and discretionary authority granted or conferred by the General Corporation Law of the State of Delaware or other statutes or laws of the State of Delaware, the Board of Directors is expressly authorized to make, alter, amend or repeal the by-laws of the Corporation, without any action on the part of the stockholders, but the stockholders may make additional by-laws and may alter, amend or repeal any by-law whether adopted by them or otherwise. The Corporation may in its by-laws confer powers upon its Board of Directors in addition to the foregoing and in addition to the powers and authorities expressly conferred upon the Board of Directors by applicable law.

ELEVENTH. The Corporation reserves the right to amend, alter, change, or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute, and all rights conferred upon stockholders herein are granted subject to this reservation.

4. This restated Certificate of Incorporation was duly adopted by the Board of Directors in accordance with Sections 241 and 245 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, said Corporation has caused this Certificate to be signed by its Board of Directors, this 7th day of June, 2002.

Robert J. Fitzsimmons

Anne D. Farrar

DIRECTORS

ELEVENTH. The Corporation reserves the right to amend, alter, change, or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute, and all rights conferred upon stockholders herein are granted subject to this reservation.

4. This restated Certificate of Incorporation was duly adopted by the Board of Directors in accordance with Sections 241 and 245 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, said Corporation has caused this Certificate to be signed by its Board of Directors, this 7th day of June, 2002.

Robert J. Fitzsimmons

Arne D. Farmer

DIRECTORS

State of Delaware
Secretary of State
Division of Corporations
Delivered 11:54 AM 04/28/2005
FILED 11:49 AM 04/28/2005
SRV 050343175 - 3527938 FILE

CERTIFICATE OF MERGER

MERGING

SELIG ACQUISITION, INC.,
a Delaware corporation

WITH AND INTO

SELIG HOLDINGS CORPORATION,
a Delaware corporation

Pursuant to Section 251(c) of the Delaware General Corporation Law (the **"DGCL"**), the undersigned corporation hereby certifies as follows:

FIRST: The name and state of incorporation of each of the constituent corporations of the merger is as follows:

Name	State of Incorporation
Selig Acquisition, Inc.	Delaware
Selig Holdings Corporation	Delaware

SECOND: An Agreement and Plan of Merger by and among Selig Intermediate Holdings, Inc., a Delaware corporation, Selig Acquisition, Inc., a Delaware corporation, Selig Holdings Corporation, a Delaware corporation, and the Securityholders (as defined therein), dated as of April 28, 2005 (the **"Merger Agreement"**), has been approved, adopted, certified, executed and acknowledged by each of the constituent corporations in accordance with Sections 251 and 228 of the DGCL.

THIRD: The name of the surviving corporation of the merger will be "Selig Holdings Corporation".

FOURTH: The Certificate of Incorporation of the surviving corporation shall be amended and restated effective as of the merger to read in its entirety in the form attached hereto as Exhibit A.

FIFTH: The executed Merger Agreement is on file at the office of the surviving corporation, the address of which is 342 East Wabash Street, Forrest, IL 61741.

SIXTH: A copy of the Merger Agreement will be furnished by the surviving corporation, on request and without cost, to any stockholder of any constituent corporation.

SEVENTH: This Certificate of Merger shall be effective upon filing with the Secretary of State of the State of Delaware.

IN WITNESS WHEREOF, Selig Holdings Corporation, the surviving corporation, has caused this Certificate of Merger to be signed by an authorized officer as of April 28, 2005.

SELIG HOLDINGS CORPORATION

By: _____

Name: STEPHEN P CASSIDY

Title: PRESIDENT & CEO

EXHIBIT A

AMENDED AND RESTATED

CERTIFICATE OF INCORPORATION

OF

SELIG HOLDINGS CORPORATION

1. The name of the corporation is Selig Holdings Corporation (the "Corporation").

2. The address of its registered office in the State of Delaware is Corporation Trust Center, 1209 Orange Street, in the City of Wilmington, County of New Castle. The name of its registered agent at such address is The Corporation Trust Company.

3. The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware.

4. The total number of shares of stock which the Corporation shall have authority to issue is 1,000 shares of common stock, par value $0.01 per share.

5. The Corporation is to have perpetual existence.

6. In furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to adopt, amend or repeal the by-laws of the Corporation.

7. Elections of directors need not be by written ballot unless the by-laws of the Corporation shall so provide.

8. Each person who is or was or had agreed to become a director or officer of the Corporation, or each person who is or was serving or who had agreed to serve at the request of the Board of Directors or an officer of the Corporation as a director or officer of another corporation, partnership, joint venture, trust or other enterprise (including the heirs, executors, administrators, or estate of such person), shall be indemnified by the Corporation to the full extent permitted by the General Corporation Law of Delaware or any other applicable laws as presently or hereafter in effect. Without limiting the generality or the effect of the foregoing, the Corporation may enter into one or more agreements with any person which provide for indemnification greater or different than that provided in this Section. Any repeal or modification of this Section 8 shall not adversely affect any right or protection existing hereunder immediately prior to such repeal or modification.

9. The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Amended and Restated Certificate of Incorporation, in the manner now or hereafter prescribed by statute, and all rights conferred upon stockholders herein are granted subject to this reservation.

State of Delaware
Secretary of State
Division of Corporations
Delivered 10:19 AM 04/29/2005
FILED 10:11 AM 04/29/2005
SRV 050346449 - 3527938 FILE

CERTIFICATE OF OWNERSHIP AND MERGER

MERGING

SELIG SEALING PRODUCTS, INC.
an Illinois corporation

WITH AND INTO

SELIG HOLDINGS CORPORATION
a Delaware corporation

Pursuant to Sections 103 and 253 of the
General Corporation Law of the State of Delaware

Selig Holdings Corporation (the "Corporation"), a corporation organized under the Delaware General Corporation Law (the "DGCL"), does hereby certify to the following facts relating to the merger of Selig Sealing Products, Inc. (the "Subsidiary"), a corporation organized under the Illinois Business Corporation Act, with and into the Corporation, with the Corporation remaining as the surviving corporation.

FIRST: The Corporation is a corporation organized under the DGCL.

SECOND: The Corporation is the owner of all of the issued and outstanding shares of capital stock of the Subsidiary.

THIRD: The Board of Directors of the Corporation on April 29, 2005, unanimously adopted resolutions authorizing the merger of the Subsidiary with and into the Corporation, pursuant to Section 253 of the DGCL. A true copy of such resolutions is annexed hereto as Exhibit A. Such resolutions have not been modified or rescinded and are in full force and effect on the date hereof.

FOURTH: In connection with the merger of the Subsidiary with and into the Corporation, the Corporation (which is the surviving corporation) is changing its name to "Selig Sealing Products, Inc."

FIFTH: This Certificate of Ownership and Merger shall be effective upon filing with the Secretary of State of the State of Delaware.

IN WITNESS WHEREOF, the undersigned corporation has caused this Certificate of Ownership and Merger to be duly executed as of this 29th day of April, 2005.

SELIG HOLDINGS CORPORATION

By: _____

Name: STEPHEN P CASSIDY

Title: PRESIDENT

Exhibit A

Resolutions adopted by the Board of Directors of the Corporation

RESOLVED: To authorize Selig Holdings Corporation (the "Company") to execute, deliver and perform the Agreement and Plan of Merger (the "Merger Agreement") by and between the Company and Selig Sealing Products, Inc. (the "Subsidiary"), an Illinois corporation and wholly-owned subsidiary of the Company substantially in the form attached hereto as Exhibit A, and any agreements, certificates, instruments or other documents referenced therein or related thereto (together with the Merger Agreement, the "Transaction Documents"); to authorize and approve the transactions contemplated in the Merger Agreement and the other Transaction Documents, including without limitation the merger of the Subsidiary with and into the Company (the "Merger"), all in accordance with and subject to the terms of the Merger Agreement and the other Transaction Documents; and that the Chief Executive Officer, Chief Financial Officer, President, Secretary or Treasurer or any Vice President of the Company (the "Authorized Officers") be, and each them acting singly hereby is, authorized to execute and deliver, on behalf of the Company, the Merger Agreement and each of the other Transaction Documents in the form as any Authorized Officer may deem necessary, appropriate, advisable or desirable, with such changes, modifications or amendments thereto as any Authorized Officer may deem necessary, appropriate, advisable or desirable, approval of which by such Authorized Officer shall be evidenced by his or her execution thereof; and that all of the foregoing is advisable and is hereby adopted, approved, certified and acknowledged.

EXHIBIT 22

State of Delaware
Secretary of State
Division of Corporations
Delivered 11:53 AM 03/06/2006
FILED 11:53 AM 03/06/2006
SRV 060216580 - 2102907 FILE

AMENDED AND RESTATED

CERTIFICATE OF INCORPORATION

OF

AAIPHARMA INC.

AAIPharma Inc., a Delaware corporation, hereby certifies as follows:

The name of the corporation is AAIPharma Inc. The name under which this corporation was originally incorporated is Applied Analytical Industries, Inc. and the date of filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware was September 29, 1986. The original Certificate of Incorporation was restated pursuant to Restated Certificates of Incorporation filed with the Secretary of State of the State of Delaware on September 25, 1996, and has been amended by Certificates of Amendment filed with the Secretary of State of the State of Delaware on June 27, 2002 and July 30, 2003. This Amended and Restated Certificate of Incorporation (the "Restated Certificate of Incorporation") was duly adopted, without the need for approval of the Board of Directors or the stockholders, in accordance with §§ 242, 245, and 303 of the Delaware General Corporation Law in accordance with a plan of reorganization of the corporation (the "Plan") approved by order of the United States Bankruptcy Court for the District of Delaware in *In re: aaiPharma Inc. et. al.*, Chapter 11 Case Nos. 05-11341 through 05-11345 and 05-11347 through 05-11350) (PJW) (Jointly Administered), under Chapter 11 of the United States Bankruptcy Code (11 U.S.C. § 101- 1330, as amended (the "Bankruptcy Code")). The Certificate of Incorporation of this corporation is hereby amended and restated to read in its entirety as follows:

ARTICLE I

Name

The name of the corporation is AAIPharma Inc. (the "Corporation").

ARTICLE II

Registered Office and Registered Agent

The address of the registered office of the Corporation in the State of Delaware is The Corporation Trust Company, 1209 Orange Street, in the City of Wilmington, County of New Castle, Delaware 19805.

ARTICLE III

Corporate Purpose

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware (the "General Corporation Law").

ARTICLE IV

(1) Capital Stock

(a) The total number of shares of stock that the Corporation shall have authority to issue is 2,000,000 shares of Common Stock, par value $.001 per share ("Common Stock"). Each holder of Common Stock shall be entitled to one vote in respect of each share of Common Stock held by such holder of record on the Corporation's stock transfer records.

(b) The holders of shares of Common Stock shall be entitled to receive, when and if declared by the Board of Directors in accordance with this Restated Certificate of Incorporation and the Bylaws, out of the assets of the Corporation which are at law available therefor, dividends payable in cash, in stock or otherwise.

(c) Except as otherwise required by statute or pursuant to the provisions of this Restated Certificate of Incorporation, as amended from time to time, the holders of Common Stock shall have the sole right and power to vote together as a single class on all matters on which a vote of stockholders is to be taken. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority in voting power of the stock of the Corporation entitled to vote generally in the election of Directors irrespective of the provisions of Section 242(b)(2) of the General Corporation Law.

(2) Non-Voting Stock

Notwithstanding anything herein to the contrary, the Corporation shall not be authorized to issue non-voting capital stock of any class, series or other designation to the extent prohibited by Section 1123(a)(6) of title 11 of the Bankruptcy Code; provided, however, that the foregoing restriction shall (i) have no further force and effect beyond that required under Section 1123(a)(6) of the Bankruptcy Code, (ii) only have such force and effect for so long as such Section 1123(a)(6) is in effect and applies to the Corporation and (iii) be deemed void or eliminated if required under applicable law.

ARTICLE V

Directors

(1) Elections of Directors need not be by written ballot, except and to the extent provided in the Bylaws.

(2) To the fullest extent permitted by Section 122(17) of the General Corporation Law, the Corporation hereby renounces any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any business opportunities that are presented to one or more of its Directors or stockholders, other than those Directors or stockholders who are employees of the Corporation.

(3) To the fullest extent permitted by the General Corporation Law, including, without limitation, as provided in Section 102(b)(7) of the General Corporation Law, as the same exists or may hereafter be amended, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the General Corporation Law is amended after approval by the stockholders of this provision to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law, as so amended. Any repeal or modification of this subclause (3) by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of such repeal or modification or with respect to events occurring prior to such time.

(4) Upon the approval of the Board of Directors, the Corporation may compensate any Director who is not an executive officer of the Corporation for such Director's service in such capacity.

ARTICLE VI

Bylaws

Except as otherwise set forth in the Bylaws, the Bylaws may be amended, supplemented or modified but only with the prior approval of at least 60% of the votes cast for such amendment by the holders of the shares of Common Stock.

ARTICLE VII

Limitation on Transfer of Shares and Related Actions

The following restrictions shall apply to any transfer of shares of Common Stock:

(1) Certain Transfers Prohibited. (a) If an individual, partnership, firm, corporation, association, trust, unincorporated organization or other entity, as well as any syndicate or group deemed to be a person under Section 14(d)(2) of the Securities Exchange Act of 1934, as amended (the "Securities Exchange Act") (each a "Person"), shall attempt to transfer in any manner whatsoever, including by way of sale, transfer, assignment, conveyance or other

disposition, including without limitation by merger, operation of law, bequest or pursuant to any domestic relations order, whether voluntarily or involuntarily, other than a sale, transfer, assignment, conveyance or other disposition by or to the Corporation, any shares of Common Stock or any option, warrant or other right to purchase or acquire shares of Common Stock (such warrant, option, or security being an "Option") (any such action being a "Transfer"), in each case, whether voluntary or involuntary, of record, by operation of law or otherwise (provided, however, that a transaction that is a pledge shall not be deemed a Transfer, but a foreclosure pursuant thereto shall be deemed to be a Transfer), then such Transfer shall be void and shall not be recognized by the Corporation unless such Transfer is (i) pursuant to an effective registration statement under the Securities Act and has been registered under all applicable state securities or "blue sky" laws (except in the case of any Transfer where the Stockholder provides to the Company such information as it may reasonably request to establish that no such registration is required because of the availability of an exemption from registration under the Securities Act and all applicable state securities or "blue sky" laws), and (ii) otherwise in compliance with this Article VII or the respective governing instruments of such securities.

(b) No Person shall Transfer any shares of Common Stock or any Options to any Person (regardless of the manner in which such Person initially acquired such shares of Common Stock or Options), nor shall the Corporation issue, sell or otherwise transfer any shares of Common Stock or Options to any Person:

(i) if the Corporation reasonably determines that such Transfer would, if effected, result in the Corporation having 300 or more holders of record (as such concept is understood for purposes of Section 12(g) of the Securities Exchange Act and any relevant rules promulgated thereunder), unless the Corporation is already subject to the reporting obligations under Sections 13 or 15(d) of the Exchange Act and any relevant rules promulgated thereunder; and

(ii) with respect to Transfers of shares of Common Stock, unless the certificates representing such shares bear legends as provided in clause (2) of this Article VII hereof for so long as such legends are applicable and such transferee (i) shall have executed and delivered to the Corporation, as a condition precedent to any acquisition of shares of Common Stock, an instrument in form and substance satisfactory to the Corporation confirming that such transferee takes such shares of Common Stock subject to all the terms and conditions of the Stockholders' Agreement (as defined in Article XIII hereof) and (ii) agrees to be bound by the terms of the Stockholders' Agreement.

The Corporation shall not transfer upon its books any shares of Common Stock to any Person except in accordance with this Restated Certificate of Incorporation and the Stockholders' Agreement.

(c) Requests for Transfer. (i) In order to provide for the effective policing of these provisions, a potential transferor or transferee who proposes to effect a Transfer, prior to the date of the proposed Transfer, must submit a request in writing (a "Request") that the Corporation review the proposed Transfer and authorize or not authorize the proposed Transfer pursuant to clause (1) hereof. A Request shall be mailed or delivered to the Secretary, General

Counsel or Chief Financial Officer of the Corporation, or any of their designees (the "Transfer Request Recipient"), at the Corporation's principal place of business or telecopied to the Corporation's telecopier number at its principal place of business. Such Request shall be deemed to have been delivered when delivered to the Transfer Request Recipient in accordance with this Restated Certificate of Incorporation. A Request shall include (A) the name, address and telephone number of the proposed transferee, (B) a description of the interest proposed to be transferred by the proposed transferee, (C) the date on which the proposed Transfer is expected to take place, (D) the name of the proposed transferor of the interest to be transferred, (E) the percentage of the proposed transferor's total interest to be transferred, (F) if applicable, reasonably sufficient information (which may, but shall not be required to, include an opinion of counsel) to establish that no registration of such proposed Transfer is required under the Securities Act and all applicable state securities or "blue sky" laws and (G) a request that the Corporation authorize, if appropriate, the Transfer pursuant to this Article VII and inform the proposed transferor and transferee of its determination regarding the proposed Transfer. Within two (2) Business Days of receipt of any Request, the Transfer Request Recipient shall make an initial determination as to whether to authorize the proposed Transfer described in the Request (it being understood that the only bases on which a Transfer may be denied are in those set out in subclauses (a)(i), (b)(i) and (b)(ii) above); provided; however; that (1) if the Transfer Request Recipient does not timely authorize or deny the proposed Transfer, such Transfer shall be deemed to be authorized hereunder, and (2) if the Transfer Request Recipient denies such proposed Transfer, then the Board, shall call a special meeting as soon as practicable, and in any case within fifteen (15) days after receipt by the Transfer Request Recipient of a Request, will act to determine whether to authorize the proposed Transfer described in the Request. Subject to subclause (2) hereof, the Board of Directors shall conclusively determine whether to authorize the proposed Transfer, in its reasonable discretion and judgment (which discretion and judgment shall be limited to the same bases as are set forth above with regard to the Transfer Request Receipt), and shall immediately inform the proposed transferee or transferor making the Request of such determination.

(ii) Authorization of Transfer of Capital Stock. Notwithstanding anything to the contrary set forth in subclause (c)(i) of this Article VII, to the extent permitted by law, the Transfer Request Recipient shall authorize a Transfer of shares of Common Stock that would result in the Company having 300 or more holders of record (as such concept is understood for purposes of Section 12(g) of the Exchange Act and any rules promulgated thereunder) if the Board has approved such a transfer. Subject to subclause (1)(b)(i) of this Article VII, the Transfer Request Recipient and the Board shall authorize (A) a Transfer by a stockholder to another stockholder, or (B) a Transfer of all shares owned by the proposed transferor to a single Person who is treated as a single record holder under the Exchange Act. For the avoidance of doubt, the Transfer Request Recipient and the Board shall approve the Transfers in the order in which the Requests are received; provided, however, that in the event that the Corporation denies a Request to Transfer any shares of Common Stock, prior to approving any subsequent Request to Transfer any shares of Common Stock, the Corporation shall provide prior notice to any stockholders who were previously denied their Request and a reasonable period of time for any such stockholders to make subsequent Requests to Transfer their shares, which subsequent Requests shall be approved in the order of which the initial Requests were previously received.

(2) Legend on Certificates. (a) All certificates for shares of Common Stock shall conspicuously bear the following legend:

THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 OR ANY STATE SECURITIES LAWS AND MAY NOT BE SOLD, PLEDGED OR OTHERWISE TRANSFERRED EXCEPT IN ACCORDANCE WITH THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT OF 1933 OR AN EXEMPTION THEREFROM AND, IN EACH CASE, IN COMPLIANCE WITH APPLICABLE STATE SECURITIES LAWS.

(b) In addition to the legend required by subclause 2(a) hereof, all certificates for shares of Common Stock shall conspicuously bear the following legend:

THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO VARIOUS CONDITIONS INCLUDING, CERTAIN RESTRICTIONS ON SALE, ENCUMBRANCE AND TRANSFER AS SET FORTH IN THE RESTATED CERTIFICATE OF INCORPORATION, AS AMENDED (THE "CERTIFICATE OF INCORPORATION"), AND THE STOCKHOLDERS' AGREEMENT DATED AS OF THE EFFECTIVE DATE (AS DEFINED THEREIN), AS IT MAY BE AMENDED FROM TIME TO TIME (THE "STOCKHOLDERS' AGREEMENT"). NO REGISTRATION OR TRANSFER OF THESE SHARES WILL BE MADE ON THE BOOKS OF THE CORPORATION UNLESS AND UNTIL SUCH RESTRICTIONS SHALL HAVE BEEN COMPLIED WITH. THE CORPORATION WILL FURNISH WITHOUT CHARGE TO THE HOLDER OF RECORD OF THIS CERTIFICATE A COPY OF THE CERTIFICATE OF INCORPORATION AND STOCKHOLDERS' AGREEMENT, CONTAINING THE ABOVE-REFERENCED RESTRICTIONS ON TRANSFERS OF STOCK, UPON WRITTEN REQUEST TO THE CORPORATION AT ITS PRINCIPAL PLACE OF BUSINESS.

(c) In the event that any shares of Common Stock shall be transferred in a transaction previously registered under the Securities Act of 1933, the Corporation shall, upon the written request of the holder thereof, issue to such holder a new certificate evidencing such stock without the legend required by subclause 2(a) endorsed thereon. In the event that the Common Stock shall cease to be subject to the restrictions on transfer of this Article VII, the Corporation shall, upon the written request of the holder thereof, issue to such holder a new certificate evidencing such stock without the legend required by subclause 2(b), as appropriate.

(3) Authority of Board of Directors to Interpret. Nothing contained in this Article VII shall limit the authority of the Board of Directors to take such other action to the extent permitted by law as it deems necessary or advisable to preserve the Corporation's status as a non-reporting company under the Securities Exchange Act.

(4) Severability. If any provision of this Article VII is judicially determined to be invalid or otherwise unenforceable, such invalidity or unenforceability shall not affect the remainder of the provisions of this Article VII, which shall be thereafter interpreted as if the invalid or unenforceable part were not contained herein, and, to the maximum extent possible, in a manner consistent with preserving the Corporation's status as a non-reporting company under the Securities Exchange Act.

(5) Merger Transactions. Notwithstanding any other provisions to the contrary, the Corporation may enter into an agreement to consolidate with or merge with or into any other corporation if such agreement is approved in accordance with subclause (2)(a) of Article XI and by the requisite vote of the holders of shares of Common Stock in accordance with this Restated Certificate of Incorporation, the Delaware General Corporation Law and any other applicable laws.

(6) Certain Actions. No Person or group of Persons acting together pursuant to a common plan or arrangement shall take any action or make any Transfer (except in compliance with subclause (1)(c) of this Article VII) in each case, whether voluntary or involuntary, of record, by operation of law or otherwise which would have the effect to cause the Corporation to be required to commence the filing of periodic reports with the SEC, or result in the Corporation having 300 or more holders of record (as such concept is understood for purposes of Section 12(g) of the Securities Exchange Act and any relevant rules promulgated thereunder), and any such action or Transfer shall be void, unless such Transfer is approved by the Board of Directors.

(7) Termination. The provisions of this Article VII shall terminate upon the earlier to occur of (i) a Qualified IPO (as defined in Article XIII hereof), and (ii) the prior approval by the holders of at least 60% of the outstanding shares of Common Stock.

ARTICLE VIII

Indemnification

(1) Right to Indemnification. Each person who was or is made a party or is threatened to be made a party to or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (hereinafter a "proceeding"), by reason of the fact that he or she or a person of whom he or she is the legal representative is or was a director, officer or employee of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of any other corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to any employee benefit plan (hereinafter an "indemnitee"), whether the basis of such proceeding is alleged action in an official capacity as a director, officer, employee or agent or in any other capacity while serving as a director, officer, employee or agent, shall be indemnified and held harmless by the Corporation to the fullest extent authorized by the General Corporation Law, as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than said law permitted the Corporation to provide prior to such amendment), against all expense, liability and

loss (including, without limitation, attorneys' fees, judgments, fines, excise taxes or penalties under the Employee Retirement Income Security Act of 1974, as amended, and amounts paid or to be paid in settlement) reasonably incurred by such indemnitee in connection therewith; provided, however, that except as provided in clause (3) of this Article VIII with respect to proceedings seeking to enforce rights to indemnification, the Corporation shall indemnify any such indemnitee seeking indemnification in connection with a proceeding (or part thereof) initiated by such indemnitee only if such proceeding (or part thereof) was authorized by the Board of Directors.

(2) Right to Advancement of Expenses. The right to indemnification conferred in clause (1) of this Article VIII shall include the right to be paid by the Corporation the expenses (including without limitation reasonable attorneys' fees) incurred in defending any such proceeding in advance of its final disposition (hereinafter an "advancement of expenses"); provided, however, that, if the General Corporation Law requires, an advancement of expenses incurred by an indemnitee in his or her capacity as a director, officer or employee (and not in any other capacity in which service was or is rendered by such indemnitee, including, without limitation, service to an employee benefit plan) shall be made only upon delivery to the Corporation of an undertaking (hereinafter an "undertaking"), by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal (hereinafter a "final adjudication") that such indemnitee is not entitled to be indemnified for such expenses under this clause (2) or otherwise.

(3) Right of Indemnitee to Bring Suit. If a claim under clauses (1) or (2) is not paid in full by the Corporation within thirty (30) days after a written claim has been received by the Corporation, except in the case of a claim for an advancement of expenses, in which case the applicable period shall be twenty (20) days, the indemnitee may at any time thereafter bring suit against the Corporation to recover the unpaid amount of the claim. If successful in whole or in part in any such suit, or in a suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the indemnitee shall be entitled to be paid also the expense (including without limitation reasonable attorneys' fees) of prosecuting or defending such suit. In (a) any suit brought by the indemnitee to enforce a right to indemnification hereunder (but not in a suit brought by the indemnitee to enforce a right of an advancement of expenses) it shall be a defense that, and (b) in any suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall be entitled to recover such expenses upon a final adjudication that, the indemnitee has not met any applicable standard for indemnification set forth in the General Corporation Law. Neither the failure of the Corporation (including its Board of Directors, independent legal counsel or stockholders) to have made a determination prior to the commencement of such action that indemnification of the indemnitee is proper in the circumstances because the indemnitee has met the applicable standard of conduct set forth in the General Corporation Law, nor an actual determination by the Corporation (including its Board of Directors, independent legal counsel or stockholders) that the indemnitee has not met such applicable standard of conduct, shall create a presumption that the indemnitee has not met the applicable standard of conduct or, in the case of such a suit brought by the indemnitee, be a defense to such suit. In any suit brought by the indemnitee to enforce a right to indemnification or to an advancement of expenses hereunder, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an

undertaking, the burden of proving that the indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article VIII or otherwise shall be on the Corporation.

(4) Non-Exclusivity of Rights. The right to indemnification and the advancement of expenses conferred in this Article VIII shall not be exclusive of any other right which any person may have or hereafter acquire under any statute, provision of this Certificate of Incorporation, provision of the Bylaws, agreement, vote of stockholders or disinterested directors or otherwise.

(5) Insurance. The Corporation may maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise against any expense, liability or loss, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the General Corporation Law.

(6) Indemnification of Agents of the Corporation. The Corporation may, to the extent authorized from time to time by the Board of Directors, grant rights to indemnification, and rights to the advancement of expenses, to any agent of the Corporation to the fullest extent of the provisions of this Article VIII with respect to the indemnification and advancement of expenses of directors, officers and employees of the Corporation.

(7) Contract Rights. The rights to indemnification and to the advancement of expenses conferred in clauses (1) and (2) shall be contract rights and such rights shall continue as to an indemnitee who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the indemnitee's heirs, executors and administrators.

(8) Effectiveness. Notwithstanding anything to the contrary herein, this Article shall not be deemed to provide any right or protection to any person with regard to any act or omission that occurred prior to the effectiveness of this Article. This clause (8) of Article VIII shall not limit any rights that any person may have pursuant to Section 15.05 of the Plan.

ARTICLE IX

Records

The books of the Corporation may (subject to any statutory requirements) be kept outside the State of Delaware as may be designated by the Board of Directors or in the Bylaws of the Corporation.

ARTICLE X

Amendment

This Restated Certificate of Incorporation may be amended, supplemented or modified only with the prior approval of at least 60% of the votes cast for such amendment by the holders of the shares of Common Stock; provided, further, that the foregoing provisions shall

not apply to amendments, supplements or modifications to Article I, Article II or Article IX hereof unless any such amendment, supplement or modification conflicts with or is inconsistent with the remaining Articles hereof.

ARTICLE XI

Significant Business Decisions

(1) Supermajority Board Approval. Notwithstanding that no vote may be required, or that a lesser percentage vote may be specified by law or by the Bylaws, or otherwise, the Corporation and the stockholders agree that the Corporation shall not take, and shall not cause or permit any Subsidiary to take, any of the following actions, in a single transaction or a series of related transactions, directly or indirectly, without the prior approval of the holders of 60% of the members of the whole Board, which, for all provisions of this clause (1) other than clause (1)(k), includes at least one member designated by the JPM Investors (as defined in Article XIII hereof) for so long as the JPM Investors maintain the right to designate two members pursuant to the Stockholders' Agreement ("Supermajority Board Approval"):

(a) except as otherwise contemplated by this Restated Certificate of Incorporation or permitted under the Management Incentive Plan (as defined in Article XIII hereof), enter into, amend or modify any agreement, lease, license, loan, or other contract (whether written or oral), or engage in any transaction outside the ordinary course of business consistent with past practice or not on an arm's-length basis, with any officer, director or Affiliate of the Corporation or any Subsidiary;

(b) except as otherwise contemplated by this Restated Certificate of Incorporation:

(i) increase by more than $2,000 in any twelve (12) month period the salary, wages, severance arrangements or other compensation of any officer, employee or consultant of the Corporation or any Subsidiary whose annual salary is or, after giving effect to such change, would be $100,000 or more;

(ii) adopt, enter into or become bound by any bonus, incentive compensation, deferred compensation, pension, profit sharing, retirement, stock purchase, stock option, stock ownership, or other employee benefit plan, practice, policy or arrangement of any kind, whether written or oral, or any employment related contract, including any Employee Stock Arrangements (as defined in Article XIII hereof) (other than the Management Incentive Plan); or

(iii) except pursuant to the Management Incentive Plan, establish or modify any (A) targets, goals, pools or similar provisions in respect of any fiscal year under any of the foregoing or any other employee compensation arrangement or (B) salary ranges, increase guidelines or similar provisions in respect of any of the foregoing or any other employee compensation arrangement.

(c) the acquisition of or other investment in (by purchase, merger or otherwise) all or any substantial portion of the assets or securities of any other company or entity, in one or a series of related transactions, involving aggregate consideration in excess of $100,000;

(d) the incurrence or guarantee of any Indebtedness (as defined in Article XIII hereof) (other than any Permitted Indebtedness (as defined in Article XIII hereof) or any Indebtedness contemplated by the most recent annual budget approved as required by subclause 1(k)) in excess of $100,000, or voluntary purchase, cancellation, prepayment or other provision for a complete or partial discharge in advance of a scheduled payment date with respect to, or waive any material right under or modify any material term of, any such Indebtedness;

(e) the voluntary incurrence of any lien, mortgage, security interest, lease, adverse claim, levy, charge or other encumbrance on assets of the Corporation or any of its Subsidiaries in excess of $100,000, except in respect of Permitted Indebtedness or purchase money obligations incurred in connection with (i) an acquisition of assets approved as required by subclause 1(c) of this Article XI or (ii) any capital expenditure approved as required by subclause 1(f) of this Article XI;

(f) make capital expenditures or enter into any other transaction not in the ordinary course of business of the Corporation which, individually or in the aggregate over any twelve (12) month period, is in excess of $100,000 (other than any capital expenditures contemplated by the most recent annual or capital budget approved as required by subclause 1(k);

(g) any voluntary recapitalization, reorganization, liquidation or dissolution the Corporation or any of its Subsidiaries other than in the course of a proceeding under the Bankruptcy Code;

(h) the issuance of any Common Equivalent Shares (as defined in Article XIII hereof) or Convertible Securities (as defined in Article XIII hereof) other than (x) in a Qualified IPO or (y) grants of options or other rights to acquire any Common Equivalent Shares or Convertible Securities under the Management Incentive Plan and issuances of Common Stock upon the exercise of any options or similar rights granted pursuant to and in accordance thereof;

(i) the redemption, purchase or other acquisition, or offer to redeem, purchase or otherwise acquire, any Common Equivalent Shares or Convertible Securities other than on a pro rata basis;

(j) the declaration or payment of any dividend or other distribution in cash or other assets (other than additional Common Stock) in respect of any capital stock of the Corporation or any Subsidiary not wholly owned by the Corporation;

(k) approve or adopt, or materially modify or amend any annual or capital budget;

(l) enter into any material joint venture, partnership or alliance with any Person; or

(m) enter into any contract, agreement, arrangement or commitment to do or engage in any of the foregoing.

(2) Supermajority Shareholder Approval. Notwithstanding that no vote may be required, or that a lesser percentage vote may be specified by law or by the Bylaws, or otherwise, the Corporation and the stockholders agree that the Corporation shall not take, and shall not cause or permit any Subsidiary to take, any of the following actions, in a single transaction or a series of related transactions, directly or indirectly, without the prior approval of the holders of not less than 60% of the outstanding Common Stock ("Supermajority Shareholder Approval"):

(a) any merger or consolidation with or into any other corporation or entity (other than transactions solely involving the merger or consolidation of a wholly-owned subsidiary with or into the Corporation or another wholly-owned Subsidiary of the Corporation);

(b) the sale, transfer or other disposition of all or substantially all of the assets or business of the Corporation and its Subsidiaries, considered on a consolidated basis, in one or a series of related transactions by way of merger, consolidation, asset sale or otherwise; or

(c) enter into any contract, agreement, arrangement or commitment to do or engage in any of the foregoing.

(3) Unanimous Board Approval. Notwithstanding anything to the contrary provided in this Restated Certificate of Incorporation, no Supermajority Shareholder Approval, shall be required for any action by the Corporation or any Subsidiary so long as such action has received the prior approval of all of the members of the Board of Directors (not including, for this purpose, any vacancies on the Board of Directors).

(5) The provisions of this Article XI shall terminate upon the earlier to occur of (i) a Qualified IPO, and (ii) the prior approval by the holders of at least 60% of the outstanding shares of Common Stock.

ARTICLE XII

Preemptive Rights

(1) In the event that the Corporation proposes to sell or otherwise issue Common Equivalent Shares or Convertible Securities, each holder of Common Stock shall have the right to acquire that number or amount of such new Common Equivalent Shares or Convertible Securities, at the price and upon substantially the same terms and conditions as such new Common Equivalent Shares or Convertible Securities are to be offered or placed by the Corporation to third parties, as shall enable such holder of Common Stock to maintain, assuming the conversion of all Convertible Securities in accordance with their terms and assuming the issuance of all Common Equivalent Shares reserved for issuance pursuant to Employee Stock Arrangements, the percentage equity interest of such holder in the Corporation immediately prior to such issuance. No such Common Equivalent Shares or Convertible Securities shall be issued

by the Corporation to any Person unless the Corporation has first offered such Common Equivalent Shares or Convertible Securities to the Stockholders in accordance with this clause (1) of Article XII. This clause (1) shall not apply to (i) the sale or issuance of Common Equivalent Shares or Convertible Securities pursuant to any Employee Stock Arrangement representing, in the aggregate, up to 10% of the Common Equivalent Shares, where the primary purpose of such plan, program or agreement is not to raise capital for the Corporation; (ii) the issuance of Common Equivalent Shares or Convertible Securities as direct consideration pursuant to any merger transaction involving the Corporation or any of its Subsidiaries or as direct consideration for the acquisition by the Corporation or any of its Subsidiaries of assets or another business entity, if such merger transaction or acquisition has received prior Supermajority Board Approval; (iii) any underwritten public offering of Common Equivalent Shares registered under the Securities Act; or (iv) pursuant to the exercise, conversion or exchange of any outstanding Convertible Securities in accordance with their terms (provided that the initial issuance of such Convertible Securities was subject to this clause (1) of Article XII).

(2) Notwithstanding anything to the contrary provided in clauses (1) and (2) of this Article XII, preemptive rights will not be available (i) to any holder of shares of Common Stock if the offer of preemptive rights to such holder would otherwise require registration under the Securities Act or any other securities laws, or (ii) if the Corporation reasonably determines that the offering of such preemptive rights would, if effected, require the Corporation to file reports of other information pursuant to Section 13 of the Exchange Act, including pursuant to Section 12(g)(1) of the Securities Exchange Act.

ARTICLE XIII

Certain Calculations; Definitions

(1) In determining whether or not a holder continues to own a certain number of shares of Common Stock, for purposes of this Restated Certificate of Incorporation, such determination shall not take into consideration dilution as a result of the issuance of any Common Equivalent Shares or Convertible Securities that are not subject to preemptive rights provided in clause (1) of Article XII.

(2) The following terms used but not otherwise defined herein shall have the definitions set forth below:

"Affiliate" means, with respect to any specified Person, any other Person directly or indirectly controlling or controlled by or under direct or indirect common control with such specified Person. For the purposes of this definition, "control" when used with respect to any specified Person means the power to direct the management and policies of such Person, directly or indirectly, whether through the ownership of voting securities, by contract or otherwise; and the terms "controlling" and "controlled" have meanings correlative to the foregoing.

"Bankruptcy Code" means Title 11 of the United States Code, 11 U.S.C. § § 101-1330.

"Common Equivalent Shares" means shares of Common Stock, and any other class or series of capital stock of the Corporation, whether or not denominated as common stock, including any series of preferred stock, which is entitled to participate in dividends and other distributions, including distributions upon liquidation, dissolution or winding-up of the Corporation, on a proportionate basis with any of the foregoing classes or series of shares (after taking into account any preference right upon liquidation).

"Convertible Securities" means any debt or equity securities (including the Common Stock), warrants, options or rights to acquire Common Equivalent Shares that, directly or indirectly, are convertible into, exercisable or exchangeable for, or otherwise represent the right to acquire receive or subscribe for, Common Equivalent Shares, with or without payment of additional consideration in cash or property, whether immediately or upon the occurrence of a specified date or a specified event, the satisfaction of or failure to satisfy any condition or the happening or failure to happen of any other contingency.

"Credit Agreement" means the Credit Agreement, dated as of the Effective Date, between the Corporation and certain of its Affiliates, the Lenders that are a party thereto (as defined therein) and Wells Fargo Bank, N.A.

"Effective Date" means March [__], 2006, upon which (i) the Effective Date as provided for in the Plan and the Confirmation Order occurred, and (ii) shares of Common Stock were issued to the stockholders pursuant to the Plan.

"Employee Stock Arrangements" means any employee stock option plan, stock purchase plan, employee benefit plan, employment contract or any similar benefit or incentive program or agreement.

"JPM Investors" means the Persons listed under the heading "JPM Investors" on Schedule A of the Stockholders' Agreement, which Persons are managed by JPMorgan Ventures Corp., a New York corporation.

"Indebtedness" of any Person means (without duplication) all obligations, whether or not contingent, of such Person (i) for borrowed money (whether or not the recourse of the lender is to the whole of the assets and properties of such Person or only to a portion thereof), (ii) evidenced by notes, bonds, debentures or similar instruments, (iii) for the deferred purchase price of goods or services (other than trade payables or other accrued current liabilities incurred in the ordinary course of business), (iv) under capital leases, (v) for reimbursement obligations under letters of credit, (vi) net obligations under interest rate protection, future, swap, cap, collar, hedge or similar agreements or arrangements or (vii) in the nature of guarantees of all or any portion of the obligations described in clauses (i) through (vi) above of any other Person (regardless of whether the foregoing items or such guarantees would appear as a liability on the balance sheet of such Person prepared on a consolidated basis in accordance with GAAP).

"Management Incentive Plan" means the stock option plan or other similar program to be established by the Board pursuant to the Plan by which the Corporation will grant options or other rights to members of the Corporation's management to purchase Common Stock in an aggregate amount not to exceed 9.51% of the Common Stock outstanding as of the

Effective Date, which stock option plan or other similar program may be amended from time to time subsequent to the date hereof in accordance with the requirements of the Stockholder's Agreement.

"Permitted Indebtedness" means any Indebtedness of the Corporation under the Credit Agreement in an aggregate amount not to exceed $45 million, any other Indebtedness between the Corporation and a wholly owned Subsidiary or between two wholly owned Subsidiaries and any other Indebtedness of the Corporation approved by Supermajority Board Approval.

"Prospectus" means the prospectus included in any Registration Statement (including a prospectus that discloses information previously omitted from a prospectus filed as part of an effective Registration Statement in reliance upon Rule 430A), as amended or supplemented by any prospectus supplement, with respect to the terms of the offering of any portion of the Registrable Shares covered by such Registration Statement and all other amendments and supplements to such prospectus, including post-effective amendments, and all material incorporated by reference or deemed to be incorporated by reference in such prospectus.

"Qualified IPO" means the first underwritten public offering pursuant to an effective registration statement covering a sale of Common Stock to the public, that (A) results in gross proceeds to the Corporation of not less than $50 million, (B) is led by a nationally recognized investment bank, and (C) results in the Common Stock being listed on a national securities exchange or quoted on NASDAQ.

"Registrable Shares" means shares of Common Stock unless (i) such securities are fully transferable under Section 1145 of the Bankruptcy Code, (ii) such securities can be freely sold and transferred without restriction under Rule 145 or any other restrictions under the Securities Act or (iii) such securities have been transferred pursuant to Rule 144 under the Securities Act or any successor rule such that, after any such transfer referred to in this clause (iii), such securities may be freely transferred without restriction under the Securities Act.

"Registration Statement" means any registration statement under the Securities Act of the Corporation that covers any of the Registrable Shares pursuant to the provisions of the Stockholders' Agreement, including the related Prospectus, all amendments and supplements to such registration statement, including pre- and post-effective amendments, all exhibits thereto and all material incorporated by reference or deemed to be incorporated by reference in such registration statement. The term "Registration Statement" shall also include any registration statement filed pursuant to Rule 462(b) to register additional securities in connection with any offering.

"SEC" means the United States Securities and Exchange Commission, or any other Federal agency at the time administering the Securities Act or the Exchange Act.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations of the SEC promulgated thereunder.

"Stockholders' Agreement" means that certain Stockholders' Agreement dated as of the Effective Date, between the Corporation and each of the stockholders party thereto and

each Person that hereafter becomes a stockholder and is required by the Stockholders' Agreement to become a party thereto.

"Subsidiary" means any Person in which the Corporation, directly or indirectly through Subsidiaries or otherwise, beneficially owns more than fifty percent (50%) of either the equity interests in, or the voting control of, such Person.

IN WITNESS WHEREOF, AAIPHARMA INC. has caused this Amended and Restated Certificate of Incorporation to be signed by Ludo Reynders, its President and Chief Executive Officer, and attested by Gregory S. Bentley, its Secretary, this 6th day of March, 2006.

AAIPHARMA INC.

By: _____
Name: Ludo Reynders
Title: President and Chief Executive Officer

ATTEST:

_____
Name: Gregory S. Bentley
Title: Secretary

State of Delaware
Secretary of State
Division of Corporations
Delivered 10:45 AM 09/21/2006
FILED 10:00 AM 09/21/2006
SRV 060869922 - 2102907 FILE

CERTIFICATE OF AMENDMENT OF AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF AAIPHARMA INC.

Under Section 242 of the
Delaware General Corporation Law

AAIPharma Inc., a Delaware corporation (hereinafter called the "**Corporation**"), hereby certifies to the Secretary of State of the State of Delaware that:

FIRST: The Amended and Restated Certificate of Incorporation (the "**Certificate of Incorporation**") of the Corporation, filed with the Secretary of State of the State of Delaware on March 6, 2006 is hereby amended as follows:

1. Replace Article XI(1)(k) in its entirety with the following:

   (k) [Intentionally omitted]

2. In Article XII(2), delete the phrase "(i) to any holder of shares of Common Stock if the offer of preemptive rights to such holder would otherwise require registration under the Securities Act or any other securities laws" and replace it with "(i) to any holder of shares of Common Stock if the Company reasonably determines that the offer of preemptive rights to such holder would otherwise require registration under the Securities Act or any other securities laws". Except as set forth in the preceding sentence, Article XII remains unmodified.

SECOND: The amendment of the Certificate of Incorporation as herein set forth, has been duly adopted in accordance with the provisions of Section 242 of the Delaware General Corporation Law.

IN WITNESS WHEREOF, the Corporation has caused this Amendment to the Certificate of Incorporation of the Corporation to be signed in its name and on its behalf by its President and Chief Executive Officer this 18th day of September 2006.

AAIPHARMA INC.

By: _____

Name: Ludo Reynders

Title: President & Chief Executive Officer

EXHIBIT 23

FULLY REDACTED

EXHIBIT 24

FULLY REDACTED

EXHIBIT 25

FULLY REDACTED

EXHIBIT 26

FULLY REDACTED

EXHIBIT 27

FULLY REDACTED

EXHIBIT 28

Orchid HEALTHCARE

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Sipcot Industrial Park, Irungattukottai,
Sriperumbudur (TK) - 602 105.
Kancheepuram District, Tamil Nadu, INDIA.

A Division of Orchid Chemicals & Pharmaceuticals Ltd.,

December 07, 2007

CERTIFIED
Via ~~Registered~~ Mail
Return Receipt Requested

Howard Solomon
Chairman & and CEO
Forest Laboratories, Inc.
909 Third Avenue
New York, NY 10022

Merz Pharma GmbH & Co. KGaA
C/o G. Patrick Sage
Hueschen & Sage, PLLC
Kalamazoo Building, Seventh Floor
107 West Michigan Avenue
Kalamazoo, MI 49007

Dr. Martin Zugel
Merz Pharma GmbH & Co. KGaA
Eckenheimer Landstrasse 100
D-60318 Frankfurt am Main
Germany

Re: Memantine Hydrochloride Tablets, 5 mg and 10 mg.
Paragraph IV Certification for U.S. Pat. 5,061,703.

Dear Sirs:

Orchid Healthcare, a Division of Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid"), is providing the following information pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act ("the Act"):

1. In order to obtain approval to engage in the commercial manufacture, use, or sale of a certain Memantine product, Orchid,

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Kancheepuram District, Tamil Nadu, INDIA.

submitted to the Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") under § 505(j) of the Act that contains the required bioavailability or bioequivalence data or information. The FDA has documented the receipt of this application and has notified Orchid accordingly.

2. The ANDA number is 90-044.

3. The established name for the Memantine product is Memantine Hydrochloride Tablets, 5 mg and 10mg. Forest Labs markets Memantine Hydrochloride tablets, 5 mg and 10 mg under the brand name Namenda®.

4. The active ingredient, strength, and dosage form of the proposed drug product is Memantine Hydrochloride, 5 mg and 10 mg tablets.

5. The ANDA indicates that Orchid intends to market the Memantine product before the expiration date of U.S. Pat. No. 5,061,703 (the '703 patent). This patent is listed by the FDA in the Orange Book.

6. The ANDA indicates that the claims of the '703 patent, are invalid and/or will not be infringed by the commercial manufacture, use, or sale of the Memantine product. Below is a detailed statement of the factual and legal bases for Orchid's conclusions. This information is supplied for the sole purpose of complying with the above-referenced statutes. Accordingly, Orchid does not waive any attorney-client privilege or work product immunity concerning the subject matter of this communication.

I. SUMMARY

Orchid's proposed memantine product will not infringe any claims of the '703 patent when properly construed. In addition, the claims of the '703 patent are invalid over the prior art, as well as under 35 U.S.C. § 101/112.

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A Division of Orchid Chemicals & Pharmaceuticals Ltd.

The '703 patent indicates that:

> Cerebral ischemia is characterized by a pathophysiological situation defined by an imbalance of neuronal stimulation mechanisms. In this context, the excessive inflow of calcium through NMDA receptor channels finally leads to the destruction of brain cells in specific brain areas (Rothmann & Olney, Trends Neurosci 10, 1989, pp. 299).
>
> Therefore, in order to treat or eliminate this pathological situation, an antagonistic intervention is required with regard to the NMDA receptor channels (Kemp et al., Trends Pharmacol, Sci. 8, 1987, pp. 414).

Col 2, ln 46-56.

The '703 patent recites that "The present invention is aimed at ... employing compounds ... exhibiting an NMDA receptor channel-antagonistic and anticonvulsive action, for use in the prevention and treatment of cerebral ischemia." Col 2, ln 67-col 3, ln 3. The '703 patent further states that "[t]his objective can be achieved according to the invention by using the 1-amino adamantanes of formula (I)." Col 3, ln 4-6.

The '703 patent asserts that the use of the claimed compounds prevents an impairment or further impairment – *i.e.*, degeneration and loss of nerve cells – following ischemia. Therefore, the recited compounds allegedly are especially suited for the prevention and treatment of cerebral ischemia after apoplexy, open-heart surgery, cardiac standstill, subarachnoidal homorrhage, transient cerebro-ischemic attacks, perinatal

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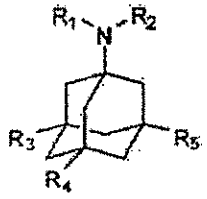
II. THE '703 PATENT

The '703 patent issued October 29, 1991 from an application filed April 11, 1990. The '703 patent claims priority to European patent application No. 89106657, filed April 14, 1989. An *ex parte* reexamination request was filed on August 18, 2004. The '703 patent reissued with amended and additional claims on November 7, 2006.

The '703 patent is listed in the U.S. Food and Drug Administration's Orange Book for Namenda®, which contains memantine as the active ingredient.

A. The Specification

The '703 patent indicates that it is directed to methods for the prevention and treatment of cerebral ischemia using an adamantane derivative of the formula



wherein R_1 and R_2 are identical or different, representing hydrogen or a straight or branched alkyl group of 1 to 6 C atoms or, in conjunction with N, a heterocyclic group with 5 or 6 ring C atoms; wherein R_3 and R_4 are identical or different, being selected from hydrogen, a straight or branched alkyl group of 1 to 6 C atoms, a cycloalkyl group with 5 or 6 C atoms, and phenyl; and wherein R_5 is hydrogen or a straight or branched C_1 -C_6 alkyl group. *See* '703 patent Abstract.

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asphyxia, anoxia, hypoglycemia, apnoea and Alzheimer's disease. The amount employed is a cerebral ischemia-alleviating or preventive amount. Col 3, ln 6-17.

The purported efficacy of the recited compounds with respect to antagonistic intervention in NMDA receptor channels is described in a series of in vitro and in vivo experiments that are detailed in the specification. Col 4, ln 55 – col 7, ln 59.

The specification concludes with various examples showing pharmaceutical compositions and methods for synthesizing different adamantane derivatives. Cols. 7 – 13.

B. The Claims

Initially Issued Claims

The '703 patent initially issued with 13 claims. Claim 1, then the only independent claim, is reproduced below

> 1. A method for the prevention or treatment of cerebral ischemia comprising the step of administering, to a patient in need thereof, an effective amount of an adamantane derivative of the general formula
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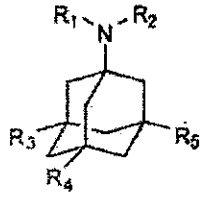
> 
>
>
> wherein
>
> R_1 and R_2 are identical or different and represent hydrogen or a straight or branched alkyl group of 1 to 6 C atoms or, in conjunction with N, a heterocyclic group with 5 or 6 ring C atoms;

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wherein

R_3 and R_4 are identical or different, being selected from hydrogen, a straight or branched alkyl group of 1 to 6 C atoms, a cycloalkyl group with 5 or 6 C atoms, and phenyl;

wherein R5 is hydrogen or a straight or branched C1 -C6 alkyl group,

or a pharmaceutically-acceptable salt thereof.

Dependent claims 2-9 describe various substituents for R_1-R_5. Dependent claims 10-13 are reproduced below.

10. A method according to claim 1 for the treatment of Alzheimer's disease.

11. A method of claim 1, wherein the adamantane derivative is administered in an effective cerebral ischemia-alleviating or preventive amount.

12. A method of claim 11, wherein the adamantane derivative is administered in the form of a composition containing the same together with a pharmaceutically-acceptable carrier or diluent.

13. A method of claim 11, wherein the adamantane derivative is administered in an amount effective to prevent degeneration and loss of nerve cells after ischemia.

Claims Issued After Reexamination

The '703 patent, after reexamination, contains nineteen claims, three of which are independent. Claims 1, 10, 14, and 17 are reproduced below. The language added during reexamination is italicized.

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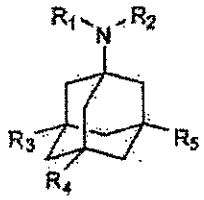
1. A method for the prevention or treatment of cerebral ischemia comprising the step of *orally* administering, to a patient *diagnosed with Alzheimer's disease and* in need thereof, an effective amount of an adamantane derivative of the general formula



wherein

R_1 and R_2 are identical or different and represent hydrogen or a straight or branched alkyl group of 1 to 6 C atoms or, in conjunction with N, a heterocyclic group with 5 or 6 ring C atoms;

wherein

R_3 and R_4 are identical or different, being selected from hydrogen, a straight or branched alkyl group of 1 to 6 C atoms, a cycloalkyl group with 5 or 6 C atoms, and phenyl;

wherein

R_5 is hydrogen or a straight or branched C_1 -C_6 alkyl group, *and*

wherein

R_1, R_2, R_3, R_4, and R_5 do not all represent hydrogen simultaneously;

or a pharmaceutically-acceptable salt thereof.

10. A method according to claim 1 for the treatment of Alzheimer's disease *wherein said adamantine derivative is memantine and said effective amount is from about 0.01 to 100 mg/kg.*

14. A method for the prevention or treatment of cerebral ischemia comprising orally administering to a patient diagnosed with Alzheimer's

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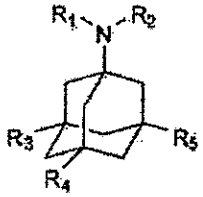
disease and in need of such treatment an effective amount of an adamantane derivative of the general formula



wherein

R_1 and R_2 are identical or different and represent hydrogen or a straight or branched alkyl group of 1 to 6 C atoms or, in conjunction with N, a heterocyclic group with 5 or 6 ring C atoms;

wherein

R_3 and R_4 are identical or different, being selected from hydrogen, a straight or branched alkyl group of 1 to 6 C atoms, a cycloalkyl group with 5 or 6 C atoms, and phenyl;

wherein

R_5 is hydrogen or a straight or branched C_1 -C_6 alkyl group, and

wherein

R_1, R_2, R_3, R_4, and R_5 do not all represent hydrogen simultaneously;

or a pharmaceutically-acceptable salt thereof.

17. A method for the treatment of an imbalance of neuronal stimulation after Alzheimer's disease, comprising orally administering to a patient diagnosed with Alzheimer's disease and in need of such treatment an effective amount of an adamantane derivative of the general formula

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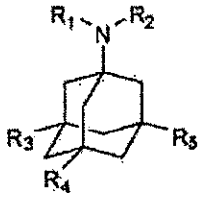

wherein

R_1 and R_2 are identical or different and represent hydrogen or a straight or branched alkyl group of 1 to 6 C atoms or, in conjunction with N, a heterocyclic group with 5 or 6 ring C atoms;

wherein

R_3 and R_4 are identical or different, being selected from hydrogen, a straight or branched alkyl group of 1 to 6 C atoms, a cycloalkyl group with 5 or 6 C atoms, and phenyl;

wherein

R_5 is hydrogen or a straight or branched C_1 -C_6 alkyl group, and

wherein

R_1 R_2 R_3, R_4, and R_5 do not all represent hydrogen simultaneously

or a pharmaceutically-acceptable salt thereof.

C. The Prosecution History

The following is not an exhaustive summary of the prosecution history of the '703 patent from the earliest filing (*i.e.* from the filing of European Application No. 89106657 filed on April 14, 1989), including reissue proceedings initiated on August 18, 2004. Rather, it is limited to a summation of certain portions of the prosecution history.

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The Initial U.S. Application

The application resulting in the initial '703 patent was filed on April 11, 1990. The application was filed with 13 claims that were, with the exception of claim 10, allowed without amendment. Claim 10, as filed, is reproduced below.

> 10. A method according to claim 1 for the prevention or treatment of Alzheimer's disease.

On January 15, 1991, the Patent Office issued an Office Action allowing claims 1-9 and 11-13, but rejecting claim 10 under §§ 101 and 112 as not enabled—as the Examiner found no support for the claim that the designated compounds "prevent Alzheimer's disease." *Office Action, Jan. 15, 1991 at 2.* Claim 10 was also rejected under § 103 as unpatentable over European Application 0227410, which disclosed that "adamantane derivatives may be used to treat Alzheimer's disease and Alzheimer dementia." *Id.* at 3.

In response, the applicants amended claim 10 by deleting the words "prevention or" from the claim to limit the claim to "treatment" of Alzheimer's disease. *Amendment, February [illegible] 1991*, at 1. The applicants also argued that EP 0227410 did not suggest that the adamantyl group was "anything like a critical substituent in the complex compounds suggested by the reference for the treatment of Alzheimer's disease or Alzheimer dementia." *Id.* at 2. Therefore, the applicants asserted, there is nothing in the reference which indicates that the adamantyl group "has anything to do with the effectiveness of the compounds claimed ... to be useful in the treatment of Alzheimer's disease or Alzheimer dementia." *Id.* at 2.

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On March 29, 1991, the Patent Office issued a Final Office Action allowing claims 1-9 and 11-13, and rejecting claim 10. The Examiner noted that no agreement had been reached regarding claim 10 during a telephonic interview. In particular, the examiner found there was "insufficient exemplary support for 'treatment of Alzheimer's disease.'"

The applicants filed a Request for Reconsideration and Withdrawal of Finality of the Final Rejection, noting that the Final Office Action contained a new basis for rejecting claim 10. In particular, the applicants noted that the Examiner initially rejected claim 10 for being directed to the prevention of Alzheimer's disease, whereas the subsequent rejection focused on the treatment of Alzheimer's disease being incredible *Request, May 20, 1991* at 1.

In response to the applicant's request for withdrawal of finality of the final rejection, the Examiner issued a Notice of Allowability of claims 1 through 13 on May 29, 1991. The '703 patent issued on October 29, 1991. On December 16, 1991, applicants filed a Request for Entry of Correction for certain typographical errors.

Request For Extension Of Patent Term—The '703 Patent

On December 9, 2003, Forest Laboratories – which is both the exclusive licensee of the '703 patent and the NDA holder for Namenda® – filed a Request for Extension of Patent Term under 35 U.S.C. § 156 for the '703 patent. Forest Labs indicated that memantine was approved by FDA on October 16, 2003 for the treatment of moderate to severe dementia of the Alzheimer's type. *Request for Patent Term Extension* at 2, 3. Forest Labs also asserted that claim 10 of the '703 patent "is explicitly directed to treatment of Alzheimer's disease, a method for using the approved product, NAMENDA™ (memantine hydrochloride), referring to claim 1 for the generic formula

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which included the approved active ingredient as explained infra. Claim 1 also covers a method of using the approved product in a generic manner." *Id.* at 5-6. Forest Labs also asserted that claims 2, 3, 6, 8, and 11-13 "cover a method for using" memantine. *Id.* at 6.

On December 27, 2006, Forest filed a Supplement to Request for Extension of Patent Term. The applicants noted that the '703 patent was reexamined by the Patent Office and as a result of the reexamination proceedings claims 1 and 10 were amended and claims 14-19 were added. *Supplemental Request for Patent Term Extension* at 1. The applicants asserted that "[a]ll information previously provided ... remains accurate. In particular, the '703 patent continues to claim a method of using [memantine], which is approved for the treatment of moderate to severe dementia of the Alzheimer's type, because claim 10 remains explicitly directed to the treatment of Alzheimer's disease and refers to independent claim 1 for the generic formula that continues to encompass memantine...." *Id.* at 2.

Request For Extension Of Patent Term—The '560 Patent

Also on December 9, 2003, Forest filed a Request for Extension of Patent Term under 35 U.S.C. § 156 for U.S. Patent No. 5,614,560.[1] In that petition, Forest again noted that memantine was approved for the treatment of moderate to severe dementia of the Alzheimer's type. *Request for Patent Term Extension* at 2. Forest Labs also asserted that "Claim 17 of the '560 patent depends from claim 1 and is specifically directed to a method of using the approved product, NAMENDA™ (memantine hydrochloride), for reducing neuronal degeneration in a mammal subject to a long-term non-ischemic

[1] The '560 patent issued March 25, 1997 from an application filed April 11, 1995. The '560 patent claims priority to an application filed on April 4, 1991. The claims of the '560 patent are directed to a method for reducing non-ischemic NMDA receptor-mediated neuronal degeneration in a mammal by administering memantine

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neurodegenerative disease, such as Alzheimer's disease (see '560 patent: col 3, lines 25-31). Claim 1 also covers a method of using the approved product in a generic manner." *Id.* at 5-6. Forest Labs also indicated that claims 2 and 4-8 "cover a method for using" memantine. *Id.* at 6.

The Reissue Application—The '703 Patent

The owner of the '703 patent filed a request for *ex parte* reexamination on August 18, 2004, on the grounds that a substantial new question of patentability might be deemed to exist under §§ 102 or 103 with respect to claims 1-3, 6, 8, and 10-13, because five prior art references were not considered during prosecution. Applicants also filed a proposed amendment to include the proviso that all the variables do not represent hydrogen simultaneously. The alleged purpose of the amendment was to exclude 1-amino adamantane from the subject matter covered by the claims.

On October 18, 2004, the Patent Office issued an Order Granting the Request for *Ex Parte* Reexamination. The Patent Office noted that the disclosed prior art references raised a substantial new question of patentability as to claims 1-3, 6, 8, and 10-13 because the disclosed prior art references teach and discuss the administration of adamantine derivatives (memantine or amantadine) for the treatment of cerebral disorders.

The Patent Office issued an Office Action dated March 10, 2005, finding claims 4, 5, 7, and 9 patentable. The Examiner rejected claims 1-3, 6, 8, and 10-13 as anticipated by the prior art references teaching that memantine is effective in treating cerebral ischemia and Alzheimer's disease or complications associated with the two disorders. *Office Action* at 2-3.

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In May 2005, applicants amended claim 1 to specify oral administration of an adamantane derivative to a patient diagnosed with Alzheimer's disease. *Amendment, May 9, 2005 at 2.* The applicants also added new claims 14-25. Claim 14 was directed to "a method for the treatment of cerebral ischemia comprising orally administering to a patient diagnosed with Alzheimer's disease and in need of such treatment an effective amount of an adamantane derivative ...." Claim 17 was directed to "a method for the treatment of an imbalance of neuronal stimulation after Alzheimer's disease, comprising orally administering to a patient diagnosed with Alzheimer's disease and in need of such treatment an effective amount of an adamantane derivative ...." Claim 20 was directed to "a method for blocking an excessive influx of calcium through NMDA receptor channels in a patient diagnosed with Alzheimer's disease ...." Claim 23 was directed to "a method for blocking the NMDA receptor in a patient diagnosed with Alzheimer's disease ...." *Id.* at 3-6.

In discussing the amended claims, the applicants noted that "[t]he present invention relates to the discovery that certain adamantane derivatives (especially memantine) can be used to treat patients diagnosed with Alzheimer's disease." *Amendment, May 9, 2005* at 8. The applicants further noted that as of May 2005, only five drugs were approved by FDA to treat patients diagnosed with Alzheimer's. Of those five drugs, none were available in 1989, and one was no longer marketed because of liver toxicity concerns. *See Id.* at 8. They also noted that memantine was the only drug approved for treatment of moderate to severe Alzheimer's disease, as well as the only such drug that did not function as a cholinesterase inhibitor. *Id.*

The Applicants also asserted that the pending claims were patentable over the prior art because the claimed methods of use provided surprising and unexpected benefits for at least three reasons: (1) in 1989, memantine was contraindicated for "severe

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confusional states," which included Alzheimer's disease patients, and was reported to cause "agitation" as a side effect, a common symptom experienced by Alzheimer's disease patients; (2) memantine was commonly believed to be a dopaminergic agent, which were thought to promote psychosis; and (3) the only published study involving the administration of memantine to Alzheimer's disease patients "plainly concluded that memantine is not effective for treatment of Alzheimer's disease." *Id.* at 10.

The Applicants argued that the Examiner improperly rejected the claims as the prior art references cited did not disclose the oral administration of memantine to a patient "diagnosed with Alzheimer's disease," as required by claim 1. Though the Applicants conceded that the Fleischhacker reference taught the administration of memantine to patients diagnosed with senile dementia of the Alzheimer type for the treatment of that condition, they argued that reference taught the administration of memantine intravenously. *See Id.* at 16-17.

Finally, the Applicants argued that the reissue claims were patentable because new claims 14-25 were narrower than the original claims, as the new claims require orally administering an adamantine derivative (claims 14-25), administering an adamantine derivative to a patient "diagnosed with Alzheimer's disease" (claims 14-25), "treatment" only (claims 14-19), treatment of an "imbalance of neuronal stimulation after Alzheimer's disease" (claims 17-19), "blocking an excessive influx of calcium through NMDA receptor channels" (claims 20-22), and "blocking the NMDA receptor" (claims 23-25). *Id.* at 17-18. The Applicants further argued that each of new claims 14-25 was patentable over the prior art because all of the claims require the step of "orally" administering an adamantine derivative to a patient "diagnosed with Alzheimer's disease." *Id.* at 18.

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The Applicants submitted two Rule 132 Declarations in support of their arguments for patentability. One declaration – from Howard Fillit, M.D. -- asserts that at the time of invention, the cholinergic approach to Alzheimer's disease treatment developed as the predominant theory, and that any proposed treatment that "strayed from this theory would have been considered extremely speculative." *Fillit Decl.* at ¶ 9. Dr. Fillit maintains that "in 1989, it would have been very surprising to find that memantine (thought to be a dopaminergic agent in 1989 and thereby unrelated to the cholinergic theory of treatment) could be successfully used for the treatment of Alzheimer's disease patients." *Id.*

Referring to the prior art relied upon by the Examiner to reject the claims, Dr. Fillit argued that "[i]f Physicians had read the [prior art references] in 1989, we would have recognized that these articles do not suggest the administration of memantine to patients diagnosed with Alzheimer's disease, which was a recognizable and diagnosable disease throughout the 1980s .... Further, by 1989, the only publication that expressly described the administration of memantine to Alzheimer's disease patients was Fleischhacker, and this article expressly concludes that memantine is not effective for the treatment of Alzheimer's disease." *Id.* at ¶ 32.

The second declaration was signed by Dr. Myron Weiner. Dr. Weiner asserted that memantine offered a number of unexpected results: (1) unexpected efficacy of a drug contraindicated for severe confusional states and having the side effect of agitation; (2) unexpected efficacy of a dopaminergic agent; and (3) unexpected existence and efficacy of NMDA antagonism. *Weiner Decl.* at ¶¶ 18-26. Dr. Weiner concluded that "[b]ased on my over 20 years experience in researching, diagnosing, and treating Alzheimer's disease patients, it was surprising and unexpected to learn that memantine could be effectively used for the treatment of patients diagnosed with Alzheimer's disease. Physicians would

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have had no reasonable expectation in 1989 that memantine could have been successfully used in this manner." *Id.* at ¶ 27.

On August 16, 2005, the Patent Office issued a Final Office Action, allowing claims 1-9 and 11-19. Claim 10 was rejected under § 112 as indefinite because it did not further limit claim 1, as amended. Claims 20-25 were rejected under § 305 as enlarging the scope of the claims of the patent being reexamined. The Examiner noted that the patent owner's amendment filed on May 9, 2005 necessitated the new grounds of rejection.

On September 26, 2005, the Examiner filed an Ex Parte Reexamination Interview Summary. The record notes simply that the outcome of the interview was embodied in an Examiner's Amendment.

On October 17, 2005, the Applicants filed an Amendment Pursuant to 37 C.F.R. §§ 1.116 and 1.530. In the Amendment, the Applicants amended claim 10 to add the limitation "wherein said adamantane derivative is memantine and said effective amount is from about 0.01 to 100 mg/kg" and cancelled claims 20-25. The Applicants also noted that in the Examiner Interview, the Examiner agreed that canceling claims 20-25 and amending claim 10 to specify the administration of memantine and its effective amount would overcome the rejection of claim 10 under § 112 and moot the rejection of claims 20-25 under § 305.

The Patent Office issued a Notice of Intent to Issue Ex Parte Reexamination Certificate on December 6, 2005. Pursuant to an Examiner's Amendment, Reissue claim 1 specifies "oral" administration of the compound to a patient "diagnosed with Alzheimer's disease," where all of the active groups (R_1, R_2, R_3, R_4, and R_5) are not all hydrogen simultaneously, and Reissue claim 10 specifies that the "adamantane derivative

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is memantine and said effective amount is from about 0.01 to 100 mg/kg." Pages 2, 3. As the reasons for allowance, the Examiner recited that the reissue claims were allowable over the prior art because those references purportedly "do not teach [that] the oral administration of ... memantine ... is effective for the prevention or treatment of cerebral ischemia in a patient diagnosed with Alzheimer's disease." Page 3.

On April 6, 2006, the Patent Office issued a Corrected Notice of Intent to Issue Ex Parte Reexamination Certificate, citing the same reasons for allowance given above.

On June 5, 2007, the Patent Office issued a Certificate of Correction to correct typographical errors.

III. NON-INFRINGEMENT ANALYSIS

A. Applicable Law

1. Claim Construction

Claims must be construed before determining whether they are valid or infringed. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976, 996 n. 7 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). Claims must be construed the same way for determining validity and infringement. *Id.* If possible, claims should be construed to uphold their validity. *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1557 (Fed. Cir. 1996).

The claim construction inquiry begins in all cases with the actual words of the claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*). Claim terms are to be given their ordinary and customary meanings as they would have been understood by a person of ordinary skill in the art in the context of the patent at the time

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of the invention, i.e., as of the effective filing date of the patent application. *Id.* at 1312-14. To properly interpret claim terms, the "intrinsic" record, including the claims, the specification and the prosecution history, must be consulted (although the prosecution history may be less useful than the claims and specification). *Id.* at 1314-24. It may also be appropriate to consider "extrinsic" evidence, i.e., evidence external to the patent and prosecution history, such as expert and inventor testimony, dictionaries, and learned treatises, although extrinsic evidence is generally less reliable than the intrinsic record. *Id.* at 1317-19 and 1322-23. While there is no "magic formula," "catechism" or "rigid algorithm" for conducting claim construction, and one is not "barred from considering any particular sources or required to analyze sources in any specific sequence," one must "attach the appropriate weight" to the various sources and may not "contradict claim meaning that is unambiguous in light of the intrinsic evidence." *Id.* at 1324. The goal is to achieve correct claim construction without imposing improper limitations on the claims. *Id.* If a claim is ambiguous even after applying all of the available claim construction tools, the claim, if possible, should be construed to preserve its validity. *Id.* at 1327-28.

"Generally, the preamble does not limit the claims." *Allen Engineering Corp. v. Bartell Industries, Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). A preamble that simply states the intended use of the claimed invention usually does not limit the scope of the claim. *See C.R. Bard, Inc., v. M3 Systems, Inc.*, 157 F.3d 1340, 1350 (Fed. Cir. 1998). "If the preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as limiting." *Allen Engineering Corp.*, 299 F.3d at 1346 (citing *Kropa v. Robie*, 187 F.2d 150, 152 (CCPA 1951)).

A dependent claim must incorporate all of the limitations of and be narrower in scope than the claim from which it depends. *See Jeneric/Pentron, Inc. v. Dillon Co., Inc.*,

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205 F.3d 1377, 1383 (Fed. Cir. 2000) (A "dependent claim, by nature, incorporates all the limitations of the claim to which it refers."); *Desper Prods., Inc. v. Qsound Labs, Inc.*, 157 F.3d 1325, 1338 n.5 (Fed. Cir. 1998) (dependent claims "necessarily must be narrower than the independent claims").

2. Infringement Law

Once a claim has been construed, it is compared to an accused product or method to determine whether that product or method infringes the claim. *Markman*, 52 F.3d at 976. To establish infringement, every claim limitation or its equivalent must be found in an accused product or method. *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29, 40 (1997). Infringement must be proved by a preponderance of the evidence. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241. If a claim "reads on" an accused product or method, *i.e.*, the accused product or method embodies each limitation set forth in the claim exactly, the accused product or method is said to literally infringe the claim. *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1996).

Infringement may also be found under the doctrine of equivalents if the accused product or method includes features that are identical or equivalent to each claimed element. *Warner-Jenkinson*, 520 U.S. at 21 and 40. The determination of equivalency, which is evaluated as of the time of infringement, is an objective inquiry applied on an element-by-element basis taking into account the role of each claim element in the context of the claim. *Id.* at 18, 29, 37 and 40.

The Supreme Court has not mandated any specific approach for evaluating equivalency. *Id.* at 39-40. Among the recognized approaches that may be applied are the so-called triple identity (function-way-result) test, the insubstantial differences test and/or

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the important objective factor of known interchangeability. *Id.* at 19-20, 25, 36 and 39-40.

There are a number of limits on the application of the doctrine of equivalents. For example, the doctrine of equivalents cannot be applied so as to effectively eliminate a claim limitation in its entirety. *Warner-Jenkinson*, 520 U.S. at 29. Moreover, limitations may not be afforded a scope of equivalency that effectively results in a claim that does not patentably distinguish the prior art. See, e.g., *Wilson Sporting Goods Co. v. David Geoffrey & Associates*, 904 F.2d 677, 683 (Fed. Cir. 1990). Additionally, prosecution history estoppel operates to prevent recapture, through the doctrine of equivalents, of coverage of subject matter that was relinquished by amendment or argument during prosecution. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733-34 (2002).

Pursuant to 35 U.S.C. § 271(b), "whoever actively induces infringement of a patent shall be liable as an infringer." Interpreting this section, the Court of Appeals for the Federal Circuit requires the plaintiff to prove that the defendant's "'actions induced infringing acts and that [they] knew or should have known [their] actions would induce actual infringement.'" *Warner-Lambert Company v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003) (citing *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990)). However, the Federal Circuit has also concluded that "'knowledge of the acts alleged to constitute infringement is not enough.'" *Id.* Rather, a finding of active inducement requires proof of actual intent to cause the acts which constitute the infringement. *Id.* Thus, "'inducement requires proof that the accused infringer knowingly aided and abetted another's direct infringement of the patent.'" *Id.* (citing *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1306 (Fed. Cir. 1999)). Inducement

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of infringement also requires the commission of an act that constitutes inducement, and not merely the power to act or the failure to act. *See Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1569 (Fed. Cir. 1994).

B. Analysis of the '703 Patent Claims

1. Construction of the '703 patent claims

According to their plain meaning, claims 1-13 are directed to, *inter alia*, a method for the prevention or treatment of cerebral ischemia comprising the step of orally administering an adamantane derivative to a patient diagnosed with Alzheimer's disease. Claims 14-16 are directed to, *inter alia*, a method for the treatment of cerebral ischemia comprising the step of orally administering an adamantane derivative to a patient diagnosed with Alzheimer's disease.

The Online Medical Dictionary[2] defines "cerebral ischemia" as "deficiency in blood supply to the brain." The specification indicates that the claims are not directed to a method of treating a deficiency in blood supply to the brain, however, but rather a method of treating or preventing degeneration and nerve loss resulting from cerebral ischemia:

> [C]erebral ischemia is characterized by a pathophysiological situation defined by an imbalance of neuronal stimulation mechanisms. In this context, the excessive inflow of calcium through NMDA receptor channels finally leads to the destruction of brain cells in specific brain areas.

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[2] Available online at: http://cancerweb.ncl.ac.uk/cgi-bin/omd?query=&action=Home.

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> Therefore, in order to treat or eliminate this pathological situation, an antagonistic intervention is required with regard to the NMDA receptor channels.

'703 *patent* at col. 2, l. 46-55 (citations omitted). The specification then explains that:

> The present invention is aimed at preparing and employing compounds which can be chemically generated by simple methods, exhibiting an NMDA receptor channel-antagonistic and anticonvulsive action, for use in the prevention and treatment of cerebral ischemia.
>
> * * * *
>
> It has been found unexpectedly that the use of these compounds prevents an impairment or further impairment, i.e., degeneration and loss of nerve cells. Therefore, the adamantane derivatives of formula (I) are especially suited for the prevention and treatment of cerebral ischemia after . . . Alzheimer's disease.

Id. at col. 2, l. 67 – col. 3, l. 16.

The '703 patent purports to show the efficacy of the claimed methods of use for the adamantane derivatives in a pharmacological test titled "Protection Against Cerebral Ischemia." '703 *patent* at col 6, ln 27-64. In that test, both carotid arteries of a rat are occluded and the blood pressure is lowered by withdrawal of blood for ten minutes. "The ischemia is terminated by opening the carotids and reinfusion of the withdrawn blood." *Id.* It was well-known that periods of cerebral ischemia lead to large increases in

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extracellular concentrations of glutamate and aspartate resulting in neuronal brain damage. *Kemp et al., TIPS, 1987, 8, 414-15.* It was also well-known that this imbalance of excitatory amino acids leads to an excessive stimulation of the NMDA receptors, leading to a lethal accumulation of intracellular calcium ions and brain cell death. *Id.* The '703 patent similarly recites that cerebral ischemia results in an imbalance of neuronal stimulation mechanisms that results in excessive inflow of calcium through the NMDA receptor channel leading to the destruction of brain cells. *'703 patent* at col. 2, l. 46-52. In discussing the carotid artery results, the '703 patent specification concludes that "the test results show that the compounds according to formula (I) exhibit a neuroprotective action in cerebral ischemia." *Id.* at col. 6, l. 58-60.

Claims 17-19 are directed to a method for the treatment of an "imbalance of neuronal stimulation after Alzheimer's disease, comprising orally administering to a patient diagnosed with Alzheimer's disease" an adamantane derivative. In the May 2005 Amendment, the applicants indicated that, "[a]s defined in the '703 patent, 'cerebral ischemia' refers to an imbalance of neuronal stimulation in which an excessive influx of calcium through NMDA receptor channels leads to degeneration and loss of brain cells." *Id.* at 18. Accordingly, the methods of claims 17-19 are directed to the treatment of cerebral ischemia in a patient diagnosed with Alzheimer's disease.[3]

The '703 patent is predicated on the notion that Alzheimer's disease (among other conditions) is a cause of cerebral ischemia. Thus, the specification indicates that the use of adamantane derivatives "prevents an impairment or further impairment, i.e., degeneration and loss of nerve cells, after ischemia," and that adamantane derivatives are

[3] Claims 17-19 differ from claim 1 (and the claims dependent thereon) because claim 1 encompass methods of "prevention or treatment of cerebral ischemia," whereas claims 17-19 are limited to methods of treatment.

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"especially suited for the prevention and treatment of cerebral ischemia after ... Alzheimer's disease." *'703 patent* at col 3, ln 7-16. In light of the plain language of the claims and the specification, the claims of the '703 patent are directed to a method for the treatment or prevention of neurodegeneration resulting from cerebral ischemia caused by Alzheimer's disease.

The prosecution history confirms that the claims of the '703 patent are directed to a method for the treatment and prevention of neurodegeneration resulting from cerebral ischemia after Alzheimer's disease. For instance, in the May 2005 Amendment, the applicants amended claim 1 to include the limitation "diagnosed with Alzheimer's disease" and referred to column 3, lines 7-16 and claim 10 as written support for that proposed claim element. The Applicants maintained that claims 14-16 were distinguished from cited prior art because the prior art did not disclose or suggest the treatment of "cerebral ischemia" and that claims 17-19 were distinguished because the prior art did not teach or suggest the treatment of an "imbalance of neuronal stimulation after Alzheimer's disease." In the August 2005 Office Action, the Examiner accepted the Applicant's arguments, indicating that "the prior art does not actually teach any of the adamantane derivatives to treat cerebral ischemia and Alzheimer's disease ***together***." *August 16, 2005 Office Action* at 2, (emphasis added). And the Examiner rejected claim 10, which at the time was directed to a "method of claim 1 for the treatment of Alzheimer's disease," for not further limiting claim 1 as amended to include the recitation "diagnosed with Alzheimer's disease." For these reasons, each of the '703 patent claims is limited to a method for preventing or treating neuronal degeneration resulting from cerebral ischemia in a patient with Alzheimer's disease.

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2. Orchid's Proposed Generic Memantine Products Will Not Infringe Any Valid Claim of the '703 Patent

(a) **Claims Encompassing Memantine**

Orchid's proposed labeling indicates that it does not seek approval for its proposed generic memantine product for the treatment of cerebral ischemia, nor will it be indicated for use in the treatment of cerebral ischemia. Nor will Orchid's proposed memantine product be indicated for the treatment of cerebral ischemia in patients with Alzheimer's disease, as required by the claims of the '703 patent. Orchid's proposed product will be indicated for treatment of dementia of the Alzheimer's type. The proposed indication for Orchid's generic memantine product accordingly is distinct from the claimed methods of the '703 patent (insofar as those claims encompass methods of using memantine) because the claimed methods necessarily involve "employing compounds . . exhibiting an NMDA receptor channel-antagonistic and anticonvulsive action, for use in the treatment and prevention of cerebral ischemia." *'703 patent* at col. 2, l. 67 – col. 3, l. 3.

Moreover, the claimed methods of the '703 patent require the use of memantine to prevent "degeneration and loss of nerve cells, after ischemia." *Id.* at col. 3, l. 9-10. Orchid's proposed product label will indicate that there is no evidence that its proposed generic memantine product "prevents or slows neurodegeneration in patients with Alzheimer's disease." In fact, there are no known methods for treating the underlying cause of Alzheimer's disease.[4] For these reasons, Orchid's proposed memantine product will not infringe any valid claim of the '703 patent.

[4] http://www.nia.nih.gov/Alzheimers/AlzheimersInformation/Treatment/.

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Orchid's proposed memantine product will not infringe any valid claim of the '703 patent under the doctrine of equivalents because attempting to do so would effectively eliminate the claim limitation "treatment of cerebral ischemia" in its entirety. Moreover, the doctrine of equivalents may not be used to encompass Orchid's proposed memantine product because doing so would create a scope of equivalency that effectively results in a claim that does not patentably distinguish the prior art. Additionally, prosecution history estoppel operates to prevent the use of the doctrine of equivalents to cover Orchid's proposed memantine product because of amendments and arguments made during prosecution. For example, the patentee is estopped from arguing that the claims of the '703 patent cover the administration of memantine for the treatment of moderate to severe dementia of the Alzheimer's type because during prosecution the applicants asserted their claims were distinguished from the prior art Fleischhacker article, which they admitted discloses the administration of memantine to treat senile dementia of the Alzheimer's type, on the grounds that the claims of the '703 patent were limited to the administration of adamantane derivatives for the treatment of cerebral ischemia and the administration of memantine for the treatment of Alzheimer's disease. *See 8/18/2004 Request for Reexamination* at 8. Forest further argued that the claims were limited to the treatment of cerebral ischemia in order to overcome a § 102 rejection. *See 5/9/2005 Amendment* at 10 & 18. The Examiner ultimately agreed, allowing the claims on the basis that "the prior art does not actually teach any of the adamantane derivatives to treat cerebral ischemia and Alzheimer's disease together." *See 8/16/2005 Office Action*. For these reasons, Orchid's proposed generic memantine product will not infringe claims 1-3, 6, 8, and 10-19 of the '703 patent.

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(b) **Claims to the Use of Compounds Other Than Memantine**

Claims 4, 5, 7, and 9 of the '703 patent are limited to methods of administering compounds other than memantine. For the general formula shown in claim 1, claim 4 requires that R_3 and R_4 be an ethyl substituent, claim 5 requires that R_3 be an ethyl, isopropyl, or cyclohexyl substituent, claim 7 requires that R_1 be a methyl or ethyl substituent, and claim 9 requires that R_3 be an ethyl substituent. As noted by Forest, memantine is represented by the general formula shown in claim 1 when R_1 and R_2 are hydrogen, one of R_3, R_4, and R_5 is hydrogen and the remaining two of R_3, R_4, and R_5 are methyl. *See Request for Extension of Patent Term, December 9, 2003* at 6. Thus, Orchid's proposed generic memantine product will not infringe claims 4, 5, 7, and 9 of the '703 patent.

IV. INVALIDITY ANALYSIS

A. Validity Law

A U.S. patent is presumed to be valid pursuant to 35 U.S.C. § 282. The presumption of validity can be overcome, but only by clear and convincing evidence that the patent is invalid. *Sibia Neurosciences, Inc. v. Cadus Pharmaceutical Corp.*, 225 F.3d 1349, 1355 (Fed. Cir. 2000). The bases for holding a patent invalid include, among others, that the claims are anticipated by or would have been obvious in view of the prior art as discussed below, that the patent specification does not fully and sufficiently describe the invention (in violation of 35 U.S.C. § 112, first paragraph), and that the claims are indefinite (in violation of 35 U.S.C. § 112, second paragraph). In the case of

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prior art-based invalidity, the clear and convincing burden of proof may be more easily met through reliance upon prior art that was not before the examiner during prosecution. *Sibia Neurosciences, id.* at 1355-56. However, patent claims nonetheless have been held invalid based upon prior art that was before the examiner. *E.g., Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1319, 1322 n.2, 1325 (Fed. Cir. 2004) (claims obvious in view of the same and cumulative prior art); *Brown v. 3M*, 265 F.3d 1349, 1351-54 (Fed. Cir. 2001) (claim anticipated by the same prior art); *Celeritas Tech. Ltd v. Rockwell Int'l Corp*, 150 F.3d 1354, 1360-61 (Fed. Cir. 1998) (claims anticipated by the same prior art).

Prior art may be in a number of forms. For example, the prior art may be (1) a patent or printed publication in the United States or a foreign country, or a public use or offer for sale in the United States, more than one year before the earliest effective U.S. filing date of the patent (35 U.S.C. §102(b)); or (2) a patent granted on, or a publication of, a patent application by another filed in the United States before the invention thereof by the applicant (35 U.S.C. §102(e)). Other examples are provided in 35 U.S.C. §102.

If all claimed elements/steps are disclosed, expressly or inherently, in a single prior art reference, that reference is said to "anticipate" the claimed invention, thereby invalidating the claim(s) under 35 U.S.C. §102 for lack of novelty. *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999). If granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless

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of whether it also covers subject matter not in the prior art. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 781 (Fed. Cir. 1985).

In the absence of an anticipatory prior art reference, the issue becomes whether "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). In determining obviousness, the following four factors must be considered: (1) the scope and content of the prior art; (2) any differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) any secondary considerations evidencing non-obviousness, such as commercial success, copying, long felt but unsolved needs, failures of others, unexpected results, etc. *KSR Intl Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1391 (2007), *citing Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).

In *KSR*, the Supreme Court confirmed that, in evaluating obviousness, "an expansive and flexible" approach is to be taken, *i.e.*, "rigid and mandatory formulas" are improper. 82 USPQ2d at 1395-97. More specifically, the Court indicated that combining prior art elements to perform their respective established functions is likely to be obvious when it does no more than yield predictable results. *Id.* at 1395. Indeed, if a design need or market pressure to solve a problem having a finite number of identified, predictable solutions provides good reason for an ordinarily skilled person to pursue the known options within his or her technical grasp, and if such pursuit leads to the anticipated success, "it is likely the product not of innovation but of ordinary skill and common sense" and "[i]n that instance the fact that a combination was obvious to try might show that it was obvious under §103." *Id.* at 1397. Conversely, when the prior art teaches

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away from combining known elements, discovery of a successful way to combine them is more likely not obvious. *Id.* at 1395.

Obviousness is not shown merely by demonstrating that each of the elements of a claimed combination was known in the art. Rather, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine [or modify] the elements" as claimed. *Id.* at 1396. However, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent" can provide such a reason, as the applicant's particular motivation/purpose does not control. *Id.* at 1397. Also, a precise teaching of claimed subject matter is not needed, as familiar items have obvious uses beyond their primary purposes, and one must consider inferences/creative steps that a person of ordinary skill ("a person of ordinary creativity, not an automaton") would have employed. *Id.* at 1396-97.

The level of skill in the art is determined entirely with reference to a hypothetical person of ordinary skill in the art presumed to be aware of all of the pertinent prior art. Relevant factors in determining the level of skill include the educational level of active workers in the field, the type of problems encountered in the art, prior art solutions to such problems, the rapidity of innovations in the art, and the sophistication of the technology. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Determination of the level of skill is often critical to determinations of whether prior art is "analogous art" and whether one of ordinary skill in the art would have been motivated to combine (or modify) prior art references. *DyStar*, 464 F.3d at 1361-63, 1370.

In order for secondary considerations evidence to be given substantial weight, the applicants must demonstrate that there is a nexus between such evidence and the merits

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of the claimed invention. *Ormco*, 463 F.3d at 1311-13; *GPAC*, 57 F.3d at 1580. In other words, such evidence must arise from the claimed invention, rather than from extrinsic influences such as unclaimed features, prior art features, marketing activities, etc. *Id.* (and cited cases).

B. Analysis of the '703 Patent Claims

I. The Claims of the '703 Patent Are Obvious in Light of the Prior Art

The claims of the '703 patent are invalid as obvious in light of the prior art. As discussed above, all claims of the '703 patent are limited to a method for preventing or treating neuronal degeneration resulting from cerebral ischemia in a patient with Alzheimer's disease. The prior art teaches both the treatment of cerebral ischemia and the treatment Alzheimer's disease patients with memantine. Taking at face value the assertions in the '703 patent that Alzheimer's disease causes cerebral ischemia and that memantine prevents neuronal degeneration resulting from the Alzheimer's-induced ischemia, then treating an Alzheimer's patient with memantine would inherently treat any neuronal degeneration resulting from the Alzheimer's-induced ischemia.

The use of memantine to treat cerebral ischemia was well-known prior to the priority date of the '703 patent. For instance, Wesemann et al, *Arzneimittelforschung*/Drug Res. 1983, 33(8), 1122 teaches that memantine is clinically useful in the treatment of cerebrovascular disorders. In addition, Weseman et al. *J Neural Transm Suppl.* 1980;(16):143 teaches that a patient with arteriosclerotic Parkinson syndrome was treated successfully with memantine. Miltner, *Arzneimittelforschung*/Drug Res. 1982, 32(10), 1268, reports that comatose patients suffering from post-traumatic cerebrovascular complications were successfully treated

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with memantine. The *Rote Liste 1986* indicates that memantine is useful to treat cerebrovascular disorders. Marcea *et al.*, *Therapiewoche*, 1988, 38, 3097-3100[5] cites to earlier studies that show that elderly patients with degenerative or vascular cerebro-organic disorders continuously show impressive improvements when given memantine.

Although the use of memantine to treat neurodegeneration resulting from Alzheimer's disease was (and still is) unknown, the administration of memantine to patients having Alzheimer's disease also was well-known prior to the priority date of the '703 patent. For example, Fleischhacker *et al.*, *Progress in Neuro-Psychopharmacology & Biological Psychiatry*, 196, 10, 87-93, describes a clinical study that administered memantine to patents who were diagnosed with senile dementia of the Alzheimer's type.

A number of other references contain similar teachings. Thus, the Marcea article describes a clinical study in which memantine was orally administered successfully to elderly patients diagnosed with moderately severe organic brain syndrome, or dementia, diagnosed according to the ICD.9 criteria. *Marcea translation* at 2. The ICD.9 criteria include dementia of the Alzheimer's type. *Fillit Declaration, May 5, 2005* at 6. Indeed, Alzheimer's disease is the most common cause of dementia; it accounts for > 65% of dementias in the elderly.[6] Thus, one of ordinary skill would have understood that most patients diagnosed with dementia are patients with Alzheimer's disease. Ambrozi *et al.*, *Pharmacopsychiatry*, 21:144-46 (1988), describes a clinical study involving geriatric inpatients diagnosed with dementia where one-half of the patients were successfully administered memantine and the other half were administered a placebo. Tempel,

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[5] Based on Forest translation submitted during reexamination of the '703 patent.

[6] The Merck Manual: http://www.merck.com/mmpe/sec16/ch213/ch213c.html?qt=dementia&alt=sh.

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Memantine Workshop March 20-21, 1987, 23-26, describes a clinical study comparing successful treatment of memantine at 10 mg per day to a more successful treatment at 20 mg per day in 60 elderly patients with an organic psychosyndrome indication. Organic brain syndrome includes dementia of the Alzheimer's type.[7] The *Rote Liste 1986* also indicates that memantine is useful to treat organic brain syndrome. Meldrum et al., *Naunyn Schmiedebergs Arch Pharmacol.* 1986, 332(1), 93-7, teaches that memantine is effective in the treatment of parkinsonism and that it enhances vigilance, short-term memory and mood in geronto-psychiatric patients. Wesemann et al, *Arzneimittelforschung*/Drug Res. 1982, 32(10), 1241-43 teaches that memantine improves disturbances of the extrapyramidal system and that it enhances parameters like vigilance, short-term memory, and mood in geronto-psychiatric patients. Thus, considering that Alzheimer's disease accounts for > 65% of the cases of dementia among the elderly such that most of the patients in these studies likely had Alzheimer's disease, one of ordinary skill would have understood that the above studies describe the successful administration of memantine to patients with Alzheimer's disease.

The foregoing references illustrate methods of using memantine to successfully treat cerebral ischemia and to successfully treat patients diagnosed with Alzheimer's disease, before the priority date of the '703 patent. Accordingly, it would have been obvious as of the effective filing date of the '703 patent application for one of ordinary skill in the art to utilize memantine to treat both conditions – *i.e.*, to orally administer memantine to prevent or treat cerebral ischemia in a patient diagnosed with Alzheimer's disease at the dosage levels set forth in the claims of the '703 patent.

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[7] http://www.nlm.nih.gov/medlineplus/ency/article/001401.htm

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2. The Claims of the '703 Patent Alternatively Are Invalid As Anticipated or Obvious

As noted, Orchid's proposed generic memantine product will not infringe any claim of the '703 patent because those claims are properly construed to claim a method for preventing or treating neuronal degeneration resulting from cerebral ischemia in a patient with Alzheimer's disease. Forest Labs appears to construe certain of the claims more broadly, however, suggesting that at least claim 10 of the '703 patent "remains explicitly directed to the treatment of Alzheimer's disease." *Supplement to Request for Extension*. Dec. 27, 2006 at 2. While that characterization ignores the plain language of the '703 patent claims (including claim 10), in the event that one or more claims of the '703 patent are construed to merely be "directed to the treatment of Alzheimer's disease," then the claims alternatively would be invalid over prior art from Fleischhacker, Marcea, Ambrozi and Tempel.

Assuming one or more of the claims of the '703 patent are construed to merely be "directed to the treatment of Alzheimer's disease," as Forest Labs has asserted, any such claims would be obvious in light of Fleischhacker, who describes a five-week clinical study that included 20 patents with an average age of 77.5 years who were diagnosed with senile dementia of the Alzheimer's type. Fleischhacker *et al., Progress in Neuro-Psychopharmacology & Biological Psychiatry*, 196, 10 at 88. Ten of the patients were treated with memantine at a daily dosage of 20 to 30 mg for a period of 35 days to determine its efficacy in the treatment of dementia of the Alzheimer's type. *Id.* at 87 – 88. The criteria used to assess outcome were the Clinical Global Impression, which assessed attention and short term memory, and the Geriatric Rating Scale and the Sandoz Clinical Assessment Geriatric, which quantified psychopathology and behavior. *Id.* at 88. In the memantine group, five patients improved, three remained the same, and only

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two deteriorated, while in the placebo group, only four patients improved, three remained the same, and three deteriorated. *Id.* at 89. While the memantine and placebo groups reportedly are not statistically distinguishable, the study's authors conclude that long-term studies could probably show clear distinction between the two groups. *Id.* at 89. The authors suggest that further studies should also be done with patients having less severe forms of dementia. *Id.* The Fleischhacker article therefore teaches a method of using memantine in the treatment of dementia of the Alzheimer's type.

Although the Fleischhacker trial involved the intravenous administration of memantine, it would have been an entirely obvious design choice as of April 1989 to administer the compound orally. For example, the Marcea reference teaches the oral administration of memantine. *Marcea translation* at 2. In fact, *Rote Liste 1986* indicates that memantine was commercially available in the form of tablets for oral administration. In addition, neither the Ambrozi nor Tempel articles indicate that patients were treated with memantine other than by oral administration. Indeed, oral administration of a drug was most commonly used because of its convenience. *See Basic and Clinical Pharmacology*, 4th ed., Katzung Ed., 1989, Appleton & Lange at p. 4. In addition, one of ordinary skill in the art would have been motivated to use orally-administrated memantine to treat patients with dementia of the Alzheimer's type because oral administration was known to result in memantine concentrations remaining in the brain for much longer periods of time compared to i.v. administration.[8] Thus, one of ordinary skill in the art would have been motivated to orally administer memantine to treat

[8] For example, Wesemann et al., *Arzneimittelforschung*; 1982;32(10):1243 describes memantine concentrations in the rat brain after both i.v. and p.o. administration. Wesemann shows that in contrast to the rapid concentration decrease in the brain after i.v. administration, a plateau is reached 1 hour after p.o. administration of memantine and maintained at least for the first 4 hours. Weseman also notes that its findings are in accordance with those seen in a human patient.

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dementia of the Alzheimer's type with an expectation of success in light of Fleischhacker.

The clinical studies and results reported on the Namenda® package insert are similar to the clinical studies described in the prior art Fleischhacker, Marcea, Ambrozi and Tempel articles—the main differences being the length of time and number of patients. The two U.S. clinical studies discussed in the package insert rely in part on measurements of Severe Impairment Battery, which measures "selected aspects of cognitive performance, including elements of attention, orientation, language, memory, visuospatial ability, construction, praxis, and social interaction." *Namenda Package Insert at 1*. The earliest of the studies reported on the Namenda® package insert is a 12-week study done in Latvia. The Latvia study enrolled 166 patients between 60 and 80 years of age that were demented as defined by DSM-III. Forty-nine percent of the patents had a Hachinski Ischemic Scale (HIS) score of less than 5 and were deemed to possibly have Alzheimer's disease, while the remaining patients with a HIS score greater or equal to 5 were deemed to have mixed type or vascular dementia. Two criteria were used to assess outcome in the Latvia study: the Clinical Global Impression of Change (CGI-C), which is the clinician's impression of severity of illness and the Behavioral Rating Scale for Geriatric Patients (BGP), which is an observer-rated scale for the assessment of functional and behavioral disturbances of geriatric patients. *See* Winblad and Poritis, *Int. J. Geriat. Psychiatry*, 1999, 14, 135. The prior art clinical studies, like the Latvia study, include geriatric patients with dementia, where a subset of the patents possibly have Alzheimer's disease. The patients in the prior art studies were evaluated using the same or similar criteria as those used in the Latvia study. And like the Latvia study, the patents treated with memantine in the prior art studies showed improvement when evaluated by similar criteria.

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Marcea *et al.*, *Therapiewoche*, 1988, 38, 3097-3100 describes a six-week clinical study involving 60 patients over the age of 55 diagnosed with moderately severe organic brain syndrome according to ICD.9 criteria, which includes dementia of the Alzheimer's type. One-half of the patients were orally administered tablets of memantine and the other half were administered a different drug. The main criteria of the study were the performance and judgment of the patients and their orientation, which were based on the following psychometric scales: the Functional Psychosis Scale B, the Plutchik Geriatric Rating Scale, and the Sandoz Clinical Assessment Geriatric Scale. The study showed a clinically relevant improvement for the patients in both groups, with the patients receiving memantine showing the most improvement. *Marcea translation* at 3-5.

Ambrozi *et al.*, *Pharmacopsychiatry*, 1988, 21, 144 describes a clinical study involving 30 inpatients diagnosed with dementia according to DSM-III where one-half of the patients were administered memantine and the other half were administered a placebo. The purpose of the study was to determine whether memantine has the ability to influence the amnestic disorders characteristic of dementia as one category of the organic mental disorders (DSM-III). The main criteria of the study were vigilance, short-term memory, and concentration, which were determined by a flicker frequency analysis, a digit span test, and mosaic test. A psychiatric rating scale was also used as a criterion. The Ambrozi article reports significant improvements in vigilance, short-term memory, and concentration for the patients administered memantine.

Tempel, *Memantine Workshop March 20-21*, 1987, 23-26 describes a nine-week clinical study comparing treatment of memantine at 10 mg per day to treatment at 20 mg per day in 60 patients between the ages of 60 and 80 with an organic psychosyndrome

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Orchid HEALTHCARE

Plot No. 83-86 & 811-814
Sipcot Industrial Park, Irungattukottai,
Sriperumbudur (TK) - 602 105.
Kancheepuram District, Tamil Nadu, INDIA.

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indication. Organic brain syndrome includes dementia of the Alzheimer's type.[9] The study used physical symptoms and psychometric scales as the two criteria to assess outcome. The study reports an equivalent improvement in both treatment groups for physical symptoms and for the Profile of Mood States, a self-evaluation scale. The study reports improvement for both groups when assessed according to the Sandoz Clinical Assessment Geriatric Scale, with the 20 mg group appearing to show more improvement that the 10 mg group.

Considering that Alzheimer's disease accounts for > 65% of cases of dementia in the elderly,[10] one of ordinary skill in the art would have understood that most of the dementia patients treated in these studies had Alzheimer's disease (or dementia of the Alzheimer's type). Indeed, in the Latvia clinical study used to support Namenda's indication for treatment of dementia of the Alzheimer's type, 49% of the patients with dementia according to DSM-III in the Latvia study were deemed to have possible Alzheimer's disease. Thus, in the event that one or more claims of the '703 patent are construed to merely be "directed to the treatment of Alzheimer's disease," such claims would be invalid as obvious over at least the prior art Fleischhacker, Marcea, Ambrozi and Tempel references.

3. The Claims of the '703 Patent Are Invalid for Lack of Enablement and/or Utility

35 U.S.C. § 112 requires that:

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[9] http://www.nlm.nih.gov/medlineplus/ency/article/001401.htm

[10] The Merck Manual: http://www.merck.com/mmpe/sec16/ch213/ch213c.html?qt=dementia&alt=sh.

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> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The Federal Circuit has held that "the enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1378 (Fed. Cir. 2007) (citations omitted). As the Federal Circuit explained "the how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention." *In re Cortright*, 165 F.3d 1353, 1356 (Fed. Cir. 1999), quoting *In re Ziegler*, 992 F.2d 1197, 1200 (Fed. Cir. 1993); *see also In re Schoenwald*, 964 F.2d 1122, 1124 (Fed. Cir. 1992) (stating that utility must be disclosed to satisfy the section 112 enablement requirement). In explaining what constitutes a sufficient showing of utility in the context of the enablement requirement, the Federal Circuit has stated that an applicant's failure to disclose how to use an invention may support a rejection under either section 112, paragraph 1 for lack of enablement, or "section 101 for lack of utility 'when there is a complete absence of data supporting the statements which set forth the desired results of the claimed invention.'" *Cortright*, 165 F.3d at 1356, quoting *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 762 (Fed. Cir. 1984).

The claims of the '703 patent require the prevention or treatment of neuronal degeneration resulting from cerebral ischemia in a patient with Alzheimer's disease or,

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alternatively, they are merely "directed to the treatment of Alzheimer's disease." In either event, "there is a complete absence of data supporting the statements which set forth the desired results of the claimed invention.'" *Cortright*, 165 F.3d at 1356. Thus, the specification of the '703 patent fails to provide any data indicating that the administration of memantine (or any adamantane derivative) effectively treats neuronal degeneration in a patient with Alzheimer's disease. Moreover, there is no data in the '703 patent that any symptoms resulting from Alzheimer's disease can be prevented or treated. The only mention of Alzheimer's disease in the specification is at the end of a list of conditions that purportedly cause cerebral ischemia. *See '703 patent at col. 3, l. 10-16*. The examples in the '703 patent are allegedly directed to showing efficacy in the prevention of the destruction of brain cells following an event of cerebral ischemia. *See id. at col. 6, l. 28-63*. There are, however, no examples directed to or evidencing neuroprotection in a patient diagnosed with Alzheimer's disease or any animal model reasonably approximating that disease state. *See id. at passim*. Indeed, the '703 patent specification is devoid of any data directed to or evidencing the notion that the referenced compounds effectively treat dementia of any type. *See id. at passim*.

The '703 patent specification does not contain data supporting the claimed use of memantine to prevent or treat neuronal degeneration resulting from cerebral ischemia in a patient with Alzheimer's disease or, alternatively, "the treatment of Alzheimer's disease" alone. There is no data of the sort set forth in the prior art references described above. In fact, there is no data of any type evidencing that memantine could be used to treat dementia. Moreover, Alzheimer's disease is a complex disease and "[w]hat causes degeneration of brain tissue in Alzheimer's disease is unknown." *Merck Manual of Health & Aging*, Section 3, chapter 27. In fact, there is no known treatment for the

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neurodegeneration associated with Alzheimer's disease.[11] The absence of information describing to one of skill in the art that the claimed invention actually prevents or treats Alzheimer's disease (or dementia of the Alzheimer's type) therefore renders the claims of the '703 patent invalid under 35 U.S.C. § 112 and/or § 101. There is no indication that one skilled in the art would accept without question the unsupported statement that the compounds identified in the '703 patent could be used to treat Alzheimer's disease (or dementia of the Alzheimer's type). Therefore, the applicants have failed to demonstrate sufficient utility and therefore cannot establish enablement. *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1323 (Fed. Cir. 2005). For these reasons, the claims of the '703 patent are invalid.

V. CONCLUSION

For the reasons discussed above, Orchid's proposed product would not infringe any valid claim of the '703 patent, either literally or under the doctrine of equivalents. Furthermore, the claims of the '703 patent are invalid in light of the prior art and for lack of enablement and/or lack of utility.

Very Truly Yours,

Dr. Billa Praveen Reddy,
Head – Pharma Research
Orchid Healthcare
A Division of Orchid Chemicals & Pharmaceuticals Ltd.

[11] http://www.nia.nih.gov/Alzheimers/AlzheimersInformation/Treatment/

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EXHIBIT 29

State of Delaware - Annual Franchise Tax Report

FILE NUMBER	CORPORATION NAME			TAX YR.	PHONE NUMBER
3864231	ORCHID PHARMACEUTICALS INC.			2006	
FEDERAL EMPLOYER ID NO.	INCORPORATION DATE	RENEWAL/REVOCATION DATE	DATE OF INACTIVITY		
	2004/10/06				

FRANCHISE TAX	$50.00 PENALTY	1.5% MONTHLY INTEREST	ANNUAL FILING FEE	PREV CREDIT OR BALANCE	PREPAID ORTV. PAYMENTS
35.00	0.00	0.00	25.00	60.00	0.00

NATURE OF BUSINESS	AMOUNT DUE	AMOUNT PAID
general	0.00	0.00

PRINCIPAL PLACE OF BUSINESS OUTSIDE OF DELAWARE

Orchid Chemicals & Pharmaceuticals Ltd., 116 Village Blvd., Suite 2

AUTHORIZED BY (OFFICER, DIRECTOR OR INCORPORATOR)	TITLE	DATE
Satish Srinivasan	Secretary	2007-03-01

REGISTERED AGENT

9000014 302/636-5401 302/636-5454

CORPORATION SERVICE COMPANY
2711 CENTERVILLE ROAD
SUITE 400

WILMINGTON DE 19808

ASSETS FOR REGULATED INVESTMENT CORPS: JAN. 1st. DEC. 31st.

AUTHORIZED STOCK BEGIN DATE	AUTHORIZED STOCK END DATE	DESIGNATION/ STOCK CLASS	NO. OF SHARES	PAR VALUE/ SHARE	NO. SHARES ISSUED	TOTAL GROSS ASSETS	ASSET DATE
04/10/06		COMMON	3,000	.000000			

OFFICER/DIRECTOR	NAME	STREET/CITY/STATE/ZIP	DATE TERM EXPIRES
Dir	K. Raghavendra Rao	c/o Orchid Chemicals & Parhmaceu 116 Village Blvd. Suite 200 Princeon NJ 085400000 US	00/00/0000
Dir	Edna Braganza	c/o Orchid Chemicals & Pharmaceuticals LTd. 116 Village Blvd., Suite 200 Princeton NJ 085400000 US	0
Dir	Satish Srinivasan	c/o Orchid Chemicals & Pharmaceuticals Ltd. 116 Village Blvd., Suite 200 Princeton NJ 085400000 US	0
Officer	Satish Srinivasan	Orchid Chemicals & Pharmaceuticals Ltd. 116 Village Blvd., Suite 200 Princeton NJ 085400000 US	00/00

PENGAD 800-631-6989

DEPOSITION EXHIBIT
ORCHID 9
6/13/08 LG

EXHIBIT 30

State of Delaware - Annual Franchise Tax Report

FILE NUMBER	CORPORATION NAME	TAX YR.	PHONE NUMBER
3864231	ORCHID PHARMACEUTICALS INC.	2004	

FEDERAL EMPLOYER ID NO.	INCORPORATION DATE	RENEWAL/REVOCATION DATE	DATE OF INACTIVITY
	/ /		

FRANCHISE TAX	$50.00 PENALTY	1.5% MONTHLY INTEREST	ANNUAL FILING FEE	PREV CREDIT OR BALANCE	PREPAID QRTY. PAYMENTS
35.00	100.00	2.03	25.00	0.00	0.00

NATURE OF BUSINESS	AMOUNT DUE	AMOUNT PAID
To conduct or engage in any lawful busi	162.03	162.03

PRINCIPAL PLACE OF BUSINESS OUTSIDE OF DELAWARE
116 Village Blvd Suite 200 Princeton NJ 08540 USA

AUTHORIZED BY (OFFICER, DIRECTOR OR INCORPORATOR) — TITLE — DATE
Satish Srinivasan — Secretary and Treasurer — 2005-03-21

REGISTERED AGENT — ASSETS FOR REGULATED INVESTMENT CORPS — JAN. 1st. — DEC. 31st.
9000014 302/636-5401 302/636-5454
CORPORATION SERVICE COMPANY
2711 CENTERVILLE ROAD
SUITE 400
WILMINGTON DE 19808

AUTHORIZED STOCK BEGIN DATE	END DATE	DESIGNATION/ STOCK CLASS	NO. OF SHARES	PAR VALUE/ SHARE	NO. SHARES ISSUED	TOTAL GROSS ASSETS	ASSET DATE
04/10/06		COMMON	3,000	.000000			

OFFICER/DIRECTOR	NAME	STREET/CITY/STATE/ZIP	DATE TERM EXPIRES
Dir	C.B.Rao	116 Village Blvd Suite 200 Princeton NJ 085400000	2999/12/31
Officer	Satish Srinivasan	116 Village Blvd Suite 200 Princeton NJ 085400000	2999/12/31

EXHIBIT 31

007370

STATE OF DELAWARE
2005 ANNUAL FRANCHISE TAX REPORT

DO NOT ALTER FILE NUMBER

FILE NUMBER	CORPORATION NAME	PHONE NUMBER
3864231	ORCHID PHARMACEUTICALS INC.	

FEDERAL EMPLOYER ID NO.	INCORPORATION DATE	RENEWAL/REVOCATION DATE	DATE OF INACTIVITY	FROM	TO
	OCTOBER 6, 2004			/ /	/ /

AUTHORIZED STOCK BEGIN DATE	ENDING DATE	DESIGNATION OR STOCK CLASS	NO. OF SHARES	PAR VALUE/SHARE	NO. SHARES ISSUED	TOTAL GROSS ASSETS	ASSET DATE	ASSETS FOR REGULATED INVESTMENT CORPS
10-06-2004		COMMON	3,000					JAN. 1st / DEC. 31st

FRANCHISE TAX	$100.00 PENALTY	1.5% MONTHLY INTEREST	ANNL FILING FEE	PREV CREDIT OR BALANCE	PREPAID CRTY. PAYMENTS	AMOUNT DUE
$ 35.00	$	$	$ 25.00	$	$	$ 60.00

REGISTERED AGENT 9000014
CORPORATION SERVICE COMPANY
2711 CENTERVILLE ROAD
SUITE 400
WILMINGTON, DE 19808

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DELAWARE SECRETARY OF STATE

CHECK NO.	AMOUNT ENCLOSED

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$100.00 PENALTY if not Received on or before
MAR 1, 2006 Plus 1.5% interest per month.

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DIRECTORS	NAME	STREET/CITY/STATE/ZIP	DATE TERM EXPIRES
1.			
2.	K. Raghavendra Rao	116 Village Blvd, Suite 200, Princeton NJ 08540	
3.	Edna Braganza		
4.	Satish Srinivasan		
5.			
6.			

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OFFICERS	NAME	STREET/CITY/STATE/ZIP	DATE TERM EXPIRES
1.	C. Bhaktavatsala Rao, Pres	116 Village Blvd, Suite 200 Princeton NJ 08540	
2.	Satish Srinivasan, Sec		

ORIGINAL SIGNATURE (OFFICER, DIRECTOR OR INCORPORATOR)	TITLE	DATE
X /s/ Satish Srinivasan, ~~Pres~~ Sec		2/28/06