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Report

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# ANNUAL REPORT 2004-2005

ZENOTECH LABORATORIES LTD.

## Board of Directors



Dr. Adipudi Ranganadha Rao  
Director



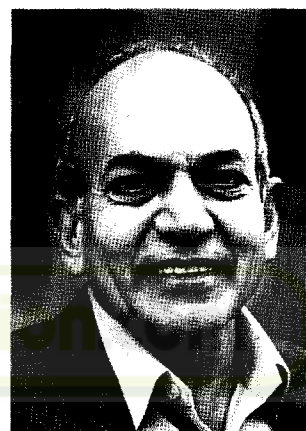
Dr. Denis Broun  
Director



Dr. Jayaram Chigurupati  
Chairman and Managing Director



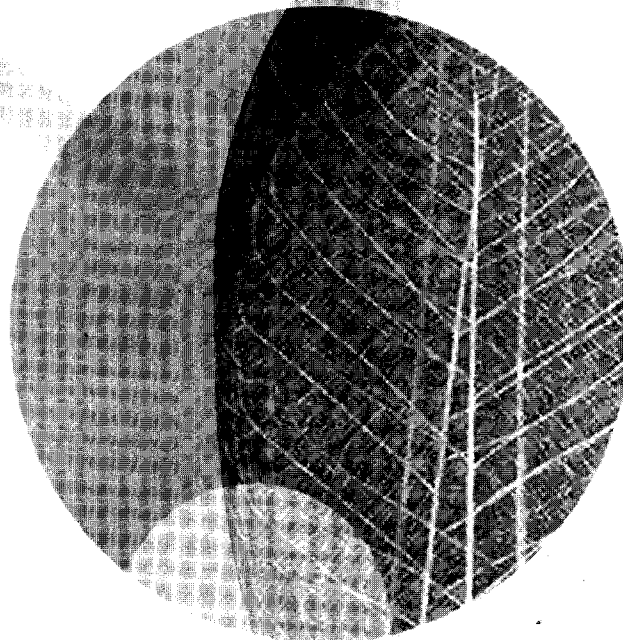
Kondapalli Ramakrishna Prasad  
Director



Prof. Vithala R. Rao  
Director



The Team that makes it all happen



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## Chairman's note

### Dear Shareholders

Every company has milestone days that vindicate its belief in a long awaited event and June 16, 2005 is one such day for Zenotech Laboratories. On this day, the European Medicines Agency (EMA) published the much awaited draft guidelines for biosimilar products like the recombinant human G-CSF. Although the framing of a draft on biosimilar products (biogenerics) was a foregone conclusion, the skeptics did not part with their views till this first revolutionary draft saw the light of the day. Zenotech however, has all along believed in

the vast potential of this exciting area and has been working incessantly to be at the forefront, to experience this exciting opportunity when the regulations for biosimilar products fall in place in the European Union and in the US markets. To take advantage of this opportunity, the Company has already developed a few biosimilar products and initiated construction of a US-FDA/EU approvable biologics manufacturing facility which is likely to be commissioned soon. It has also initiated discussions with strategic partners, who will enable Zenotech to launch rG-CSF and other biosimilar products in European Union countries as and when the draft guidelines become a law.

Zenotech Laboratories is fast emerging as a specialty generic injectables company with a biotech core. The company has launched more than ten chemical oncology injectables in India and plans to launch several more products during the year. Zenotech's two biosimilar oncology products, rGM-CSF and rG-CSF, are in final stages of Phase III clinical trials that are likely to receive marketing approval in the next few months. A third biosimilar oncology product, rIL-2 has just entered Phase III clinical trials.

Zenotech Laboratories started its international operations by setting up a wholly owned subsidiary in Brazil. The Company's Brazilian facility has received ANVISA approval in June, 2005. It is currently in the process of filing product registration dossiers for obtaining marketing approval for sales in Brazil. Zenotech has a subsidiary in Nigeria to market products in West Africa and a representation office in Vietnam, where the marketing operations of chemical oncology products began in July, 2005. The international operations are a part of the Company's BRIMS strategy in emerging markets. Brazil, Russia, India, Mexico and South Africa are core countries where the Company plans to have its own sales force to market products.

In addition to its own marketing efforts, your Company's efforts to have strategic partners for US and EU will enable it to satisfy unmet medical needs around the globe and make it a formidable specialty generic injectables company with a biotech core of biosimilar products.

Best wishes,

Dr. Jayaram Chigurupati

## BUILDING STRENGTHS IN SPECIALTY GENERICS

Worldwide, generic pharmaceuticals industry is experiencing an unprecedented growth due to patent expiry of innovator products, spiraling health care costs in regulated markets and increased affordability of drugs by the consumers in emerging markets.

Pharmaceutical companies are adopting various strategies for growth in revenues and profitability. While some generic companies are fortifying their long established dominant position in commodity generics, others are building their strengths in developing specialty generics and new value added formulations of existing products.

Among the specialty generic companies there are again niche players. Some see a lot of merit in adopting a pure play biogenerics approach while others would like to place their bets on a combination strategy that includes biogenerics and high value generic chemical products. Besides, many generic companies have also realized the need to develop proprietary molecules to enable them to move up the value chain. All this has led to large pharmaceutical companies adopting multi-pronged approaches to gain leadership positions in the generic pharmaceutical industry. The differentiating factor would lie in the strategic decision taken by individual companies with respect to individual areas not only of pricing, sales and marketing but even as diverse as R&D and innovation.

Futuristic vision of being a forerunner in this area has prompted Zenotech Laboratories to build its strength in the area of specialty generics. Zenotech has positioned itself as a specialty generic injectables company with a biotech core. Its strategy is to use generic biopharmaceuticals as core products and complement them with chemical products in specific therapy areas like oncology, gynecology and neurology.

Zenotech foresees the continued development of injectable biogenerics and other value added specialty generic products, as being the key to its future. The Company seeks to attain a position in the higher echelons of the generic biopharmaceuticals value chain through continuous innovation, niche marketing, strategic alliances and global operations. The marketing infrastructure being set up in Brazil, Russia, India, Mexico and South Africa (BRIMS) amongst other emerging markets is the initial step in the direction of globalizing the Company's operations.

## PREDOMINANTLY HIGH VALUE INJECTABLE PRODUCTS PIPELINE

Zenotech's predominantly high value injectables comprise product pipelines that serve niche therapy areas like oncology, gynecology and neurology. The product portfolios are therapy area specific and each basket of products has generic biologicals at its core complemented by generic chemical drugs from the same therapy area, thereby providing unique therapy basket of generic products fulfilling unmet medical needs.

Generic biological products are developed completely in-house by a highly qualified and trained team that uses recombinant DNA technology and cGMP production methods. They provide customers with generic versions of biopharmaceuticals that are comparable to the original innovator brand in quality, safety and efficacy. Three of the generic biological products developed so far in oncology, GM-CSF, G-CSF and IL-2 are presently in clinical trials at different centers in India. The first two products GM-CSF and G-CSF are likely to be launched in 2005. The third product has entered clinical trials and will be launched next year.

Zenotech has the unique distinction of being the first Indian company to initiate clinical development of a generic monoclonal antibody, Rituximab, an oncology product for the treatment of non-Hodgkins lymphoma. Several other generic biopharmaceuticals are in various stages of development.

Given below are a few biopharmaceuticals that are in clinical/preclinical development:

Biopharmaceutical injectable formulations	Therapeutic area	Status
GMCSF	oncology	Phase III multi-centric clinical trial
GCSF	oncology	Phase III multi-centric clinical trial
IL-2	oncology	Phase III multi-centric clinical trial
Rituximab	oncology	Preclinical

The Company has launched 12 chemical oncology products in India and intends to launch several other oncology products this year.

### Chemical oncology injectable formulations

S. No.	Brand Name	Generic Name	Strength	Cancer
1	ZENOZAR	Gemcitabine	200 mg and 1 gm	Lung, Pancreatic
2	OXIDACH	Oxaliplatin	50 mg and 100 mg	Colorectal
3	IRNOZEN	Irinotecan HCl trihydrate	40 mg and 100 mg	Colorectal, SCLC
4	ZENOTAX	Paclitaxel	30 mg, 100 mg, 250 mg and 300 mg	Ovarian, Breast
5	ZENOTERE	Docetaxel	10 mg, 80 mg, 120 mg	Breast, Lung
6	BLEOZEN	Bleomycin Sulphate	15 IU	Sarcomas, Ovarian
7	RUBIZEN	Epirubicin HCl	10 mg and 50 mg	Breast, AML
8	ZENOFOS	Combination of Ifosfamide + Mesna	2 mg	Testicular
9	ZENOCARB	Carboplatin	150 mg and 450 mg	Ovarian
10	ETOZEN	Etoposide	100 mg	Testicular
11	ZENOPLAT	Cisplatin	10 mg and 50 mg	Solid tumours

## THE ROAD SO FAR

Period	Achievement
May, 2003	Biotech R&D facilities set up
July, 2003	Research scientists recruited for biotech R&D; development of generic biologicals initiated
October, 2003	Approval for initiating rDNA work by Zenotech taken up by RCGM Committee of DBT, Ministry of Science and Technology
September, 2003	Industrial license to set up a manufacturing facility for biotech products obtained
November, 2003	Completed clone development of four therapeutic proteins; transferred clones for process development
March, 2004	<ul style="list-style-type: none"> <li>Received approval for conducting animal toxicity studies for three biotech oncology products</li> <li>Received DSIR recognition for in-house R&amp;D centre</li> </ul>
April, 2004	First generic chemical oncology product, Zenozar, launched
May 2004	<ul style="list-style-type: none"> <li>Completed animal toxicity studies for all the three biotech oncology</li> <li>Approval sought for the three biotech oncology products for conducting human clinical trails from GEAC, Ministry of Environment and Forests, Delhi</li> <li>Consent Order for Establishment from APPCB</li> </ul>
June, 2004	Oxidach and Irnozen products launched
July, 2004	<ul style="list-style-type: none"> <li>Zenotax product launched</li> <li>Approval obtained for conducting animal toxicity studies for fourth biogeneric product</li> <li>GEAC approval obtained for the first two biotech products</li> </ul>
August, 2004	<ul style="list-style-type: none"> <li>Zenotere product launched</li> <li>Work begins on biologicals manufacturing facility</li> </ul>
September, 2004	Bleozen product launched
October, 2004	Rubizen product launched
November, 2004	Approval obtained from DCGI, Ministry of Health for conducting human clinical trials for two biotech oncology products
January, 2005	<ul style="list-style-type: none"> <li>Clinical trials for two of biogeneric products, GM-CSF and G-CSF, initiated</li> <li>Initiates international marketing infrastructure in Brazil, Zenotech Farmaceutica Do Brasil Limitada</li> </ul>
February, 2005	Receives RCGM, DBT approval for carrying out pre-clinical toxicity studies on generic version of Rituximab, a monoclonal antibody
March, 2005	Zenofos, Zenocarb, Etozen and Zenoplat products launched

## BOARD OF DIRECTORS

### **Dr. Adipudi Ranganadha Rao**

Director

Dr. Ranganadha Rao joined the Company as Director in June 2004 prior to which he was a Director in Zenotech Laboratories Pvt. Ltd.

Dr. Ranganadha Rao is an M.S., M.Ch., (Urology). He was Professor and Head of the Department of Genito Urinary Surgery, Osmania Medical College and Hospital, Hyderabad. Dr. Rao is a practicing urologist and is credited with the first kidney transplantation in the State of Andhra Pradesh in 1982.

### **Dr. Denis Broun**

Director

Dr. Broun joined the Company as Director in August 2004 prior to which he was a Director in Zenotech Laboratories Pvt. Ltd. He is closely associated with the United Nations in the area of health management programs worldwide. He is currently the Head of UNAIDS in New Delhi. His previous positions as Managing Director of Management Sciences for Health, Europe, Program Manager and Chief of Health and Special Advisor to the Executive Director at UNICEF, Health Financing Specialist and Senior Health Specialist at the World Bank have involved inter-agency communication and coordination in fields ranging from infectious diseases to child health.

Dr. Broun obtained his Masters in Biomathematics and Medical Doctor Degree from the University of Paris. He then specialized in Tropical Medicine from Institut Leon M'Ba, University of Paris and holds Diploma cum Magna laude of the Paris Institute of Political Sciences.

### **Dr. Jayaram Chigurupati**

Chairman and Managing Director

Dr. Jayaram joined the Company as Director in October 2003. Dr. Jayaram was associated with recombinant proteins and biogenerics for the past eight years. Earlier, Dr. Jayaram has had a stint as Associate Consultant with The Wilkerson Group, New York City and as Technology Transfer Consultant at the Center of Advanced Technology Cornell University, Ithaca, New York. He was also a founder and Vice President of Viral Therapeutics, Inc, New York, where his responsibilities included development and marketing of recombinant proteins for therapeutic and diagnostic use.

Dr Jayaram was also the Senior/Executive Vice President of Emerging Businesses (Biotechnology, Oncology and Diagnostics) and International Branded Formulations Marketing at Dr Reddy's (RDY). He has been instrumental in establishing Dr Reddy's presence in many emerging markets of the world. He was also the Managing Director of Zenovus Biotech (a wholly owned subsidiary of Dr. Reddy's).

Dr. Jayaram holds an MBA from Cornell (1994) and a PhD in Biochemical Genetics (1988).

**Kondapalli Ramakrishna Prasad**

Director

Mr. Ramakrishna Prasad joined the Company as Director in October 2003 prior to which he was a Director in Zenotech Laboratories Pvt. Ltd. He has more than three decades of experience in media and publishing industry. He has successfully led a number of publications from their inception to commercial success including Udayam daily news paper. He brings in rich experience of handling the intricacies of the media and publishing businesses.

Mr. Ramakrishna Prasad has a Bachelor of Science degree from Andhra University.

**Prof. Vithala R. Rao**

Director

Prof. Vithala Rao joined the Company as Director in August 2004. Prof. Rao started his career as Assistant Professor of Marketing and Quantitative Methods at Johnson School of Management, Cornell University in 1970 and became a Professor in 1977. Since 1991, Prof. Rao is the Deane W. Malott Professor of Management at Cornell. Prof. Rao teaches marketing strategy, marketing research, marketing models and brand management. He teaches at various foreign universities including Indian School of Business, Hyderabad. He also teaches in executive education programs in the U.S. and other countries.

Prof. Rao has consulted for several corporations in the US and abroad. He serves on the editorial boards of Marketing Science and Journal of Marketing Research. Prof. Rao has published in Journal of Marketing Research, Journal of Marketing, Journal of Consumer Research, Management Science, Marketing Letters, Applied Economics, International Journal of Research in Marketing, and Marketing Science in the areas of conjoint analysis and multidimensional scaling for the analysis of consumer preferences and perceptions, pricing, market structure, bundling, and brand equity. He is the co-author of books, Applied Multidimensional Scaling, Decision Criteria for New Product Acceptance and Success, New Science of Marketing, and Analysis for Strategic Marketing.

Prof. Vithala R. Rao has a Master's in Sociology from University of Michigan (1962) and a Ph.D. in Applied Economics/Marketing from Wharton School of Management, University of Pennsylvania (1970).

## CORPORATE GOVERNANCE

Zenotech Laboratories Limited ("Zenotech" or the "Company") believes that the system of Corporate Governance protects interests of all the stakeholders by inculcating transparent business operations and accountability. The Company's philosophy on Corporate Governance ensures the fullest commitment of the Board of Directors and Management. The Company envisages the attainment of the highest level of transparency, accountability and equity in all facets of its activities and operations.

### Board of Directors

#### Composition

The Board of Zenotech Laboratories Limited consists of a Managing Director who is also the Chairman of the Company and four eminent persons as Independent Non-Executive Directors from different fields such as medicine, marketing, finance and public health.

The Board of the Company meets at regular intervals for planning, assessing and evaluating all important business activities. The Board has constituted an Audit Committee, Shareholders'/Investors' Grievances Committee and Remuneration Committee.

#### Attendance of each Director at Board Meetings and last Annual General Meeting (AGM)

The Board met eight times during the financial year 2004-05:

S. No.	Name of the Director	Category of Directorship	No. of Board Meetings held in the year during the tenure of the Director	No. of Board Meetings attended	Attendance at the last AGM held on September 30 <sup>th</sup> , 2004	Out-side Directorships
1.	Dr. A. Ranganadha Rao	Independent Non-Executive Director	7	7	Yes	-
2.	Dr. Denis Broun <sup>(1)</sup>	Independent Non-Executive Director	3	2	No	1
3.	Dr. Jayaram Chigurupati	Chairman and Managing Director	8	8	Yes	4
4.	K. Ramakrishna Prasad	Independent Non-Executive Director	8	8	Yes	4
5.	Kosaraju Venkatadri <sup>(2)</sup>	Independent Non-Executive Director	8	3	No	-
6.	K. Satyanarayana	Independent Non-Executive Director	8	4	No	4