



*Enhancing the quality of life*


**ANNUAL  
REPORT  
2005-2006**

**Zenotech Laboratories Limited**



Cytotoxic formulations facility - 100% EOU



 zenotech  
PRESENTING

Midazolam Injection

To pacify your patients

**UNCON**<sup>TM</sup>

Propofol Injection

The safest propofol

**CurioMie**<sup>TM</sup>

Rocuronium Injection

The most flexible NMBA

**NUMBLOK**

Atracurium Injection

The most widely used  
non-depolarizing muscle relaxant

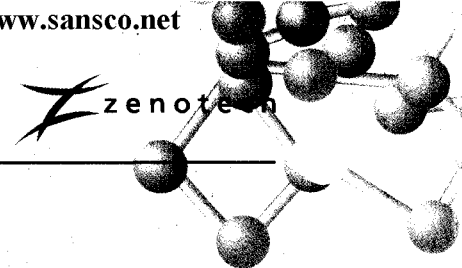
Vecuronium Injection

Most widely used muscle relaxant

**SERAG**<sup>TM</sup>

Granisetron Injection

The new approach in the  
management of PONV



# Contents

## Contents

Chairman's note	01
Specialty injectables - gearing up for the US market	02
Board of Directors	09
Corporate Governance	11
Director's Report	25
Management's discussion and analysis	31
Financial statements	
- Auditor's Report	34
- Balance sheet	38
- Profit and loss account	39
- Cash flow statement	40
- Schedules forming part of balance sheet and profit and loss account	41
- Balance sheet abstract	56
Consolidated financial statements	58
Section 212 report	76
Financials - Zenotech Farmaceutica Do Brasil Ltda., Brazil	77
Financials - Zenotech Laboratories Nigeria Limited, Nigeria	81
Financials - Zenotech Inc., USA	83
Notice of the Annual General Meeting	89
Glossary	93
Proxy form and attendance slip	94

## CHAIRMAN'S NOTE

*Dear Shareholders*

*We are in exciting times for generic biologicals and Zenotech is building on the base created so far to take advantage of the evolving regulatory environment.*

*Your company is first in India to launch a generic version of GM-CSF. GM-CSF along with G-CSF will enable oncologists to choose appropriate drug when treating cancer patients. Your company, again, will be first in India when it launches generic IL-2 in India used for treating renal cell carcinoma, in a few months. Your company has initiated clinical development of generic rituximab, a generic monoclonal antibody used for treating non-Hodgkin's lymphoma. Generic rituximab along with several other generic monoclonal antibodies developed by the research and development team, in-house, will propel your company to be a formidable player in generic biologicals.*

*Your company has operationalized a US FDA approvable biologics manufacturing facility. This facility will enable us to not only produce generic biologics from E.coli and mammalian cell cultures, but also formulate them in the fill-finish facility. The facility is already manufacturing biologics like G-CSF and GM-CSF along with other non-cytotoxic small volume parenterals. This facility is gearing up to produce exhibit batches of non-cytotoxic parenterals for ANDA filings in the US later this year.*

*Your company entered into anesthesiology therapy area by launching several injectables in general anesthesiology. Your company is striving to be one of the leading players in anesthesiology by adding more products in the coming months. This is part of your company's strategy to specialize in specialty injectables.*

*Your company's research team has been developing new biologic entities in cancer that are patentable. These monoclonal antibodies are currently in preclinical development and will enter clinical development from Phase I stage within the next one year. Your company's achievement will not only serve unmet medical needs of cancer patients but also make Zenotech a full fledged biopharmaceuticals company; from generic biologicals to generic monoclonal antibodies to new biological entities.*

*Going forward, your company will initiate clinical development of G-CSF for European union through a strategic collaboration, start filing ANDA in the US for non-cytotoxic injectables and initiate clinical development of at least one new biopharmaceutical product in oncology.*

*Best Wishes,*

A handwritten signature in dark ink, appearing to read 'Ch. J.' followed by a stylized flourish.

*Dr. Jayaram Chigurupati*

## SPECIALTY INJECTABLES - GEARING UP FOR THE US MARKET

Zenotech aims to grow by building and sustaining a position of leadership in specialty injectables across its entire product range; from generic pharmaceutical drugs to biopharmaceuticals. The synergies between these two areas will help in faster expansion of the business in the domestic and international markets. It plans to achieve this growth by setting up world class manufacturing facilities and promoting in-house development of different technology platforms. In the years to come, these twin aspects are likely to help Zenotech in not only achieving a leadership status in specialty injectables but in also winning a place among the low cost manufacturers of the world.

### SMALL VOLUME PARENTERALS

Infrastructure, Products and Team – the essence of the Company

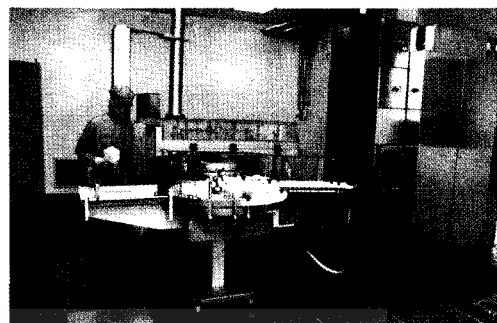
Zenotech started its operations by setting up a manufacturing plant for production of cytotoxic products in oncology. This cytotoxic formulation facility spread over a space of 14,000 sq. ft. has since catered to not only in-house manufacturing requirements for over thirty products but also for contract manufacturing needs of several collaborators.

This cGMP compliant facility has the capacity to manufacture cytotoxic small volume parenteral drugs. It is equipped with a vial filling line that can fill about 60 vials per minute, a freeze drier (2 m<sup>2</sup>) that can handle about

9,000 vials per batch and all associated equipments like the soiling and labeling machines and cold cabinets for finished product storage. The production staff are capable of efficient planning and scheduling of the manufacturing activities, addressing in house and outside customers' contract manufacturing needs.

A dedicated oncology oral dosage forms facility that is 3,600 square feet and is capable of manufacturing tablets and capsules and package them in bottles and blister packs is being built as per the US FDA/EU norms. The facility can produce up to 100,000 doses of capsules or tablets per batch.

Zenotech has launched several cytotoxic products in the domestic market and in emerging markets.



Formulation manufacturing filling line



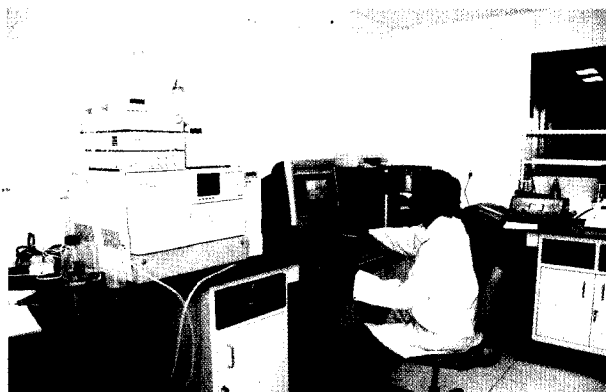


## Zenotech's oncology brands

Generic Name	Brand Name	Strengths
Docetaxel Trihydrate	ZENOTERE	20mg, 80mg, 120mg
Gemcitabine HCL	ZENOZAR	200mg, 1000mg
Ifosfamide	ZENOFOS	1000mg, 2000mg
Irinotecan HCL Trihydrate	IRNOZEN	40mg, 100mg
Oxaliplatin	OXIDACH	50mg, 100mg
Paclitaxel	ZENOTAX	30mg, 100mg, 250mg, 300mg
Vinorelbine Tartrate	VINOROL	10mg, 50mg
Vincristine sulfate	VINZEN	1mg, 2mg
Bleomycine sulfate	BLEOZEN	15IU
L-Asparaginase	ASGINASE	5000 IU, 10000 IU
Carboplatin	ZENOCARB	150mg, 450mg
Cisplatin	ZENOPLAT	10mg, 50mg
Cytarabine	LEUCOBINE	100mg, 500mg, 1000mg
Doxorubicin HCL	RUBIDOX	10mg, 50mg
Epirubicin HCL	RUBIZEN	10mg, 50mg
Etoposide	ETOZEN	100mg
Fluorouracil	FLURA-5	250mg, 500mg
Methotrexate	ZENTREX	15mg, 50mg, 500mg, 1000mg
Dacarbazine	DAXIN	100mg, 200mg
Leucovarin Calcium	LEUCOCAL	15mg, 50mg, 100mg
Idarubicine HCL	IDACIN	5mg, 10mg
Mitoxantrone HCL	MIZON	20mg, 30mg
Mitomycin-C	ZENOMYCIN	2mg, 10mg
Fludarabine phosphate	FLUBINE	50mg
Vinblastine sulphate	BLASTINE	10mg

### Process development for API manufacture by organic synthesis - a heady start

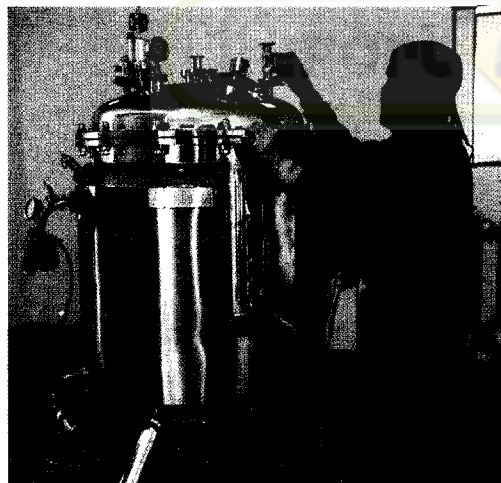
The synthetic API R&D division develops cost-effective processes for manufacture of generic drug molecules. The processes for synthesis of two molecules, Gemcitabine hydrochloride, a chemotherapy drug and Zoledronic acid, used in hypercalcemia of malignancy, are now in use for regular production batches. The processes for a few chemotherapy drugs like Docetaxel and Paclitaxel are at the scale-up stage of development, which is likely to be followed by several other chemotherapy molecules like Irinotecan, Oxaliplatin, and Topotecan. These achievements are due to the efforts of a team of fifteen qualified and experienced personnel. They operate in a 6,500 sq.ft. area of a state-of-the-art facility equipped with the reactors, fume hoods, rotary evaporators and pumps for conducting multi-stage reactions.



API Quality Control

### Formulations Development - an exciting time

The process development activity does not stop with the development of a process for API bulk production. The formulation development team takes on where the bulk team leaves off, coping with the challenges of freeze drying and drug delivery (PEGylation, liposomal and depot formulations). This team has been instrumental in developing new or improved processes for formulation of several molecules in oncology and anesthesiology, for in-house and outside customers.



Buffer preparation

A highlight has been the method to manufacture multi-dose formulation of propofol – the first of its kind in India. Among several other challenging projects taken up by the team, a few of them deserve special mention; the formulation development for L-asparaginase and a new process for the manufacture of epirubicin and bleomycin are among them. Several process improvements instituted by the team has helped in quality improvements of products like gemcitabine and zoledronic acid injections. In one way or the other, the team has been responsible for the launch of the entire anesthesiology range of products at Zenotech.

### Zenotech's Anesthesiology Products

Generic Name	Brand Name	Strength
Midazolam	PACIMID	5mg, 10mg
Rocuronium Bromide	CUROMID	25mg, 50mg, 100mg
Atracurium besolate	NUMBLOK	50mg, 100mg
Vecuronium Bromide	VECMID	4mg, 10mg, 20mg
Propofol	UNCON	100mg, 200mg, 500mg
Granisetron HCL	SERAG	3mg

### Zenotech's – Other Products

Generic Name	Brand Name	Strength
Omeprazole	OMEZENO	40mg
Mesna	MESNZ	600mg, 1200mg
Zoledronic acid	BLASTOZEN	4mg
Pantoprazole sodium	PANTOZEN	40mg
Vancomycin HCL	VANCOZEN	500mg, 1000mg
Enoxaparin sodium	ZENOXARIN	20mg, 40mg, 60mg, 80mg
Amifostine	FOSTINE	500mg
Pamidronate di sodium	PAMID	30mg, 60mg, 90mg

In addition to the cytotoxic and anesthesiology products, Zenotech has developed several products in other therapy areas as well. These products are listed in the table above and have again been the outcome of the superior efforts of the formulations development team.

### Beyond the borders, the lure of global markets

The support from the analytical R&D and the regulatory teams have been instrumental in helping Zenotech to make the leap forward into markets beyond our borders. A cGMP compliant Analytical R&D division equipped with HPLCs, GCs, polarimeters, potentiometers and other sophisticated instruments, has been instrumental in developing and validating test methods for product registrations in India and other countries.

The expansion in product line-up was planned concurrently with expansions into new markets. Zenotech's oncology products are already available in Vietnam and will now be available in several other countries outside India. Several product registrations undertaken in emerging markets of Venezuela, Costa Rica, Peru, El Salvador, Honduras, Philippines, Thailand, Malaysia, Nigeria, Kenya, Algeria, Sudan, and Sri Lanka will enable the Company to gain momentum in expanding and establishing a global presence.



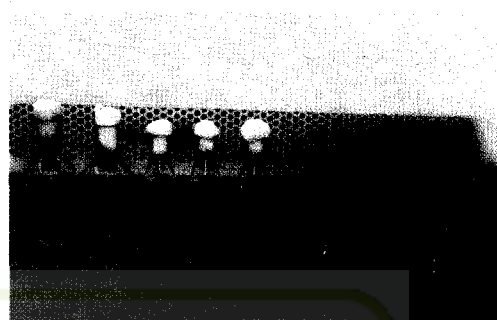
*A Second Oncology Small Volume Parenterals Manufacturing, a 100% Export Oriented Unit - a grand finale*

The construction of a new cytotoxic manufacturing facility that is US FDA/EMEA approvable is now in progress. This facility with an area of 48,000 square feet, will house manufacturing, warehouse, packaging, QC, R&D and service areas. This facility when completed will have an integrated vial filling line that can handle all the vial fill-finish operations from vial washing and sterilization to filling and stoppering at a speed of about 4,800 vials per hour. It will also have an automated freeze drier (20 m<sup>2</sup>) that can produce 10,000 vials (50 ml vials) per batch. This facility has been designed to handle pilot and production scale batches for the US and EU collaborators including Ranbaxy.

## GENERIC BIOPHARMACEUTICALS

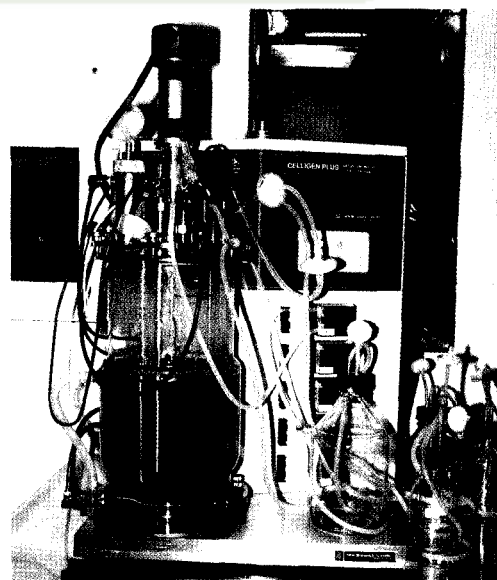
Generic Biologicals Development, products and team - at the core of Zenotech

The biologicals R&D team develops new and generic biological drugs using an integrated recombinant DNA platform covering areas of molecular and cell biology, protein purification, fermentation technology and monoclonal antibody technologies. This department has teams in different areas of product, process and formulations development, working in synchrony to take a biological drug product from start to commercial launch. The four main areas of work are generic biologicals (therapeutic proteins and monoclonal antibodies), generic formulations and drug delivery systems, generic peptide drugs and new therapeutic humanized monoclonal antibodies.



Cell cultures

During the year, several milestones were reached with the generic biologicals group completing the technical and regulatory requirements for launching G-CSF (Nugraf™) and GM-CSF (Macrogen™), the completion of pre-clinical animal toxicology studies for two generic biologicals, recombinant human Growth Hormone and generic rituximab and human clinical trials for generic Interleukin-2. The next significant goal post will be the clinical trial studies on generic rituximab, Zenotech's first generic monoclonal antibody for non-Hodgkins lymphoma. Besides this, there is also an exciting pipeline of several generic monoclonal antibody therapeutics in development, with the generic version of another block buster molecule 'Herceptin' (generic name transtuzumab) coming up soon.



R & D *E.coli* fermentation

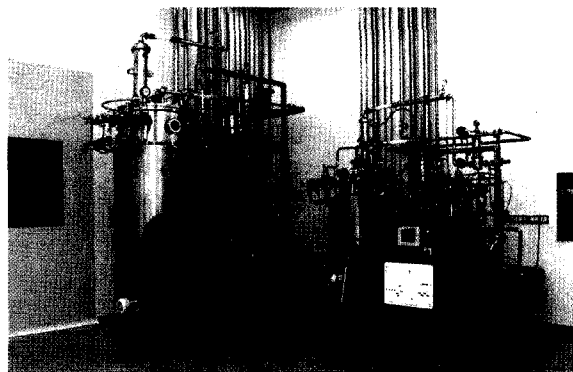
From generic protein therapeutics to generic peptide molecules, the expansion into this related area was imminent all along, but it was only during the year that establishing the infrastructural requirements for synthesizing and characterizing peptide drugs took a firm shape. Several generic peptide oncology drugs will soon add variety to the existing biologicals product basket.

There have been a few other creditable achievements by the biologicals R&D team, like the method for preparation of a novel pegylated G-CSF by the formulations development team and the work on novel humanized monoclonal antibodies initiated by the new drug discovery team. All these activities are likely to provide a steady supply of drugs in the biologicals pipeline and also establish different technology platforms within the R&D, that can be of immense value in future to the Company.

## ANNUAL REPORT 2005-2006

*Generic Biologicals Manufacturing Facility - a proud asset*

The US FDA approvable biologics bulk and formulations manufacturing facility is a unique asset for the Company rivaled by none other in this country. Built on a 51,000 sq. ft. area, it has segregated bulk and formulation-fill finish areas. The bulk API manufacturing area has two different modules for production of recombinant proteins from microbial and mammalian hosts. Each module is complete with its own fermentation, purification, support areas, equipments and utilities. The microbial fermentors with a capacity of 100L (expandable to 350L) and the mammalian bioreactors with a capacity of 600L (that can be increased to 2400L) have been installed in each of these modules along with other major equipments like



Mammalian cell culture

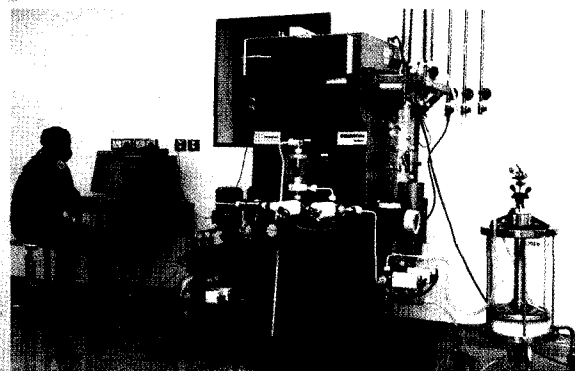


Downstream processing

high pressure homogenizers, continuous centrifuge, chromatography systems and membrane filtration modules which are not shared between the microbial and mammalian production modules. The microbial module being used for the manufacture of G-CSF and GM-CSF molecules, is also available for contract manufacturing of biological API for collaborators.

The formulation fill-finish area in the Biologicals facility has an integrated vial filling line with a vial washer, sterilizing tunnel, automated filling and stoppering operations, a syringe filling line and a freeze drier (2 m<sup>2</sup>) with all

necessary utilities like HVAC, purified water, steam, compressed air, chilled water, and UPS are available for the bulk and formulation areas. Integral to the manufacturing areas are the support areas housing the raw material stores, dispensing and sampling areas, packing material stores, finished goods stores, administration and training areas.



Purification