#### **Notice**

Notice is hereby given that the Nineteenth Annual General Meeting of the Members of M/S TRANSGESNE BIOTEK LIMITED will be held on Thursday, the 30th September, 2010 at 11.00 A.M. at 68, 69 & 70, Anrich Industrial Area, Bollaram, Medak District, to transact the following business.

#### **ORDINARY BUSINESS:**

# 1. ADOPTION OF AUDITED ACCOUNTS AND REPORTS

To receive, consider and adopt the Balance Sheet as at 31st March, 2010, the Profit and Loss Account for the year ended as on that date, Directors' Report and Auditors' Report thereon.

#### 2. RE-APPOINTMENT OF DIRECTOR

To appoint a Director in place of Dr P K Ghosh who retires by rotation and being eligible offers himself for reappointment.

#### 3. RE-APPOINTMENT OF DIRECTOR

To appoint a Director in place of Sri P Narayana Murthy who retires by

rotation and being eligible offers himself for reappointment.

#### 4. APPOINTMENT OF AUDITORS

To consider and if thought fit to pass the following resolution with or without modification(s) as Ordinary Resolution:

"RESOLVED THAT M/S Sarath & Associates, Chartered Accountants, be and are hereby re-appointed as Auditors of the Company to hold the office from the conclusion of this Annual General Meeting of the Company until the conclusion of next Annual General Meeting of the Company at a remuneration to be fixed by the Board of Directors in consultation with the Auditors."

By the Order of the Board For **Transgene Biotek Limited** 

Sd/-

Dr.K.Koteswara Rao

Place : Hyderabad Chairman & Chairman & Managing Director

### NINETEENTH ANNUAL REPORT 2009-10

#### **Notes:**

- A member entitled to attend and vote at the meeting is entitled to appoint one or more Proxies to attend and vote on a poll instead of himself.
- 2. The Proxy need not be a member of the Company.
- 3. Should any member choose to exercise his right of appointing a Proxy, the Proxy Form attached herewith should be duly completed and should be deposited at the Registered Office of the Company not less than 48 Hours before the time of holding of the meeting.
- 4. Member/Proxies should bring the Attendance Slip duly filled in for the attending the meeting.
- 5. Members are requested to bring their copies of the report and accounts of the Company.
- 6. The Register of Members and Share Transfer Books of the Company will remain closed from Tuesday the 28th September 2010 to Thursday the 30th September, 2010 (both days inclusive).

### **Directors' Report**

The Board of Directors of your Company hereby present the 20th Annual Report on the business & operations of the company and Audited Statement of Accounts for the year ended 31st March, 2010 along with the Auditor's Report thereon.

#### **FINANCIAL RESULTS**

Rs. in Lakhs

Particulars Particulars	2008-09	2009-10
Net Sales / Income	398.46	370.02
Total Expenditure	234.42	217.29
Gross Operating Profit	164.04	152.73
Interest & Financial Charges	84.98	75.37
Depreciation	33.49	34.81
Profit before Tax/Loss	45.57	42.55
Provision for Tax	7.42	4.82
Net Profit	38.15	37.73

#### **OPERATIONS**

During the year under review the total income was Rs.398.46 Lakhs as against Rs.370.02 Lakhs in the previous year and the Net Profit for the year was Rs.38.15 Lakhs as against Rs.37.73 Lakhs for the previous year. During the year, the company has incurred an amount of Rs.455.77 lakhs on ongoing product development and Rs.10.05 Lakhs on Fixed Assets as against Rs.239.09 lakhs and Rs.13.14 Lakhs respectively in 2008-09.

During the year gone by, your company has been advancing on several fronts especially on the product development aspect. This is highly satisfying for a company like Transgene where the core focus is the development of novel and exciting Biotechnology products with first of their kind on the global scene. In order to mitigate the risks involved in developing such novel products

and also, to strengthen your company's revenues the management has been focusing on the development of technologies and commercialization of some API drugs too. As you already know one of your API drugs, Orlistat, has already been out-licensed to Dr Reddy's Laboratories Limited (DRL) and the first two installments have been received as a part of the upfront payment schedule - with the remaining upfront payments and royalties on the commercial sales to be received from the current year onwards.

Soon after the technology transfer to DRL for Orlistat is completed, the production facilities shall be utilized for producing other API drugs which have been put on hold during the last several months.

#### DIVIDEND

Your Directors are unable to recommend any dividend for the year due to inadequacy of profits.

#### **GROWTH PLANS AND OUTLOOK**

This year we hope to complete the scaling up process of the manufacture of Orlistat – which in turn will lead to a new stream of revenues emanating from Royalties paid to Transgene by Dr Reddy's Labs. At the moment that process is on-going, and although the scaling up process has taken a little longer than expected we anticipate moving to the next level of that process very soon. Problems with this process have included contamination of production batches - something that Transgene has taken specific corrective steps to eliminate. Over the next few weeks and months the completion of that process will see us visit Dr Reddy's Orlistat manufacturing plant in Eastern Europe.

Moving onto the other API's, as you can understand we chose to direct all our API resources to the Orlistat project and so made

- a conscious decision to put the other projects in this division on hold... that includes Tacrolimus and one or two other APIs also. To reiterate, once the scaling-up process of Orlistat is completed work on these other projects will resume. As reported earlier your company's management is actively pursuing to set-up a large production facility with the help of funding from SBIRI, Department of Biotechnology, Government of India to enhance the revenue generation and bottom line of your company.
- 2. Last year we reported that Transgene had reached some critical milestones in the development of our therapeutic AIDS vaccine. That progress has continued this year and we are now on the verge of entering preclinical trials. We have begun technology optimization process of our immuno-toxin drug in preparation for preclinical toxicology and efficacy studies. Added to the revenues we expect through royalties from DRL deal, and the prospects for the out-licensing of our AIDS vaccine during the next calendar year the future seems very bright indeed.
- 3. On the development of Oral Insulin, due to a combination of financial constraints and the fact that your other projects (including the Oncology drugs and the AIDS vaccine) are progressing at a far greater pace, we decided to put this project on hold for the time being. We fully intend to resume work on this front once financial constraints are eased from completion and sale of one of our technologies, or from the successful raising of funds.
- 4. Moving on to the real pride of your company, namely the Oncology division comprising of the siRNA drugs and the Monoclonal Antibody drugs, your directors draw distinct pleasure in telling you how

- well these projects are progressing. Within a relatively short space of time we have managed to create a world class oncology pipeline here at Transgene Biotek. With our siRNA drugs we have begun our search for third party CRO companies with whom we will be working to conduct animal efficacy and preclinical toxicology studies for our Liver cancer and Breast cancer drugs. This validation by an external CRO will add a significant degree of integrity and value to our pipeline something that should give all of you, our trusted shareholders the confidence that we are creating enormous value here in your company.
- 5. Equally pleasing are the strides we are making in the development of the monoclonal antibody drugs – again, within the oncology division of your pipeline. Within just a few days from now we expect to receive the report from a third party CRO company who have been given the task of validating our in-house studies conducted on four drugs - for Colon cancer, Multiple Myeloma, Non-Hodgkins Lymphoma and Esophageal cancer. This will not only serve to enhance the value of our claims on the efficacy of your pipeline, but will also provide Transgene with a host of data which can be submitted to regulatory authorities (or other interested parties) when necessary.
- 6. The medical centers have been performing steadily on the expected lines.
- 7. As we reported in recent weeks, your Board has agreed to acquire Marillion Pharmaceuticals Inc., of Pennsylvania, USA in an all-share deal. However, this deal is subject to satisfactory due diligence to be conducted on Marillion Pharmaceuticals Inc. One of the main strengths perceived in this deal is Marillion's pipeline of 3 oncology products, two of which are said

to be at Phase I human trials stage, and the third one at Phase II. The perception carried by your management in trying to acquire this company is not only to enhance Transgene's reputation as a specialist R&D oncology company, but also extends the company's pipeline from preclinical to clinical as well. Added to the expanded product list, the merger is expected to bring with it the skills and experience of Marillion's CEO Dr Zahed Subhan, an expert on IND filing and US FDA related matters. In addition, your company's management felt that this deal also brings Transgene Biotek closer to the Venture Capital community, a feature that will help Transgene's capital raising efforts going forward. However, the management is acutely aware that the consummation of this deal is subject to a satisfactory due diligence to be carried out by a team of experts appointed by your company's management on Marillion Pharmaceuticals from various angles.

In conclusion, the overall changes mentioned above in the stated business of your company are likely to make significant contributions to the company's bottom line from the next few months onwards. Add to this the acquisition of Marillion, which also instantly creates a presence in western markets with an enhanced, even more lucrative pipeline – it becomes obvious why we feel so confident about the company's prospects.

#### **EMPLOYEES STOCK OPTION SCHEME**

The employee stock option scheme is still under implementation.

#### **DIRECTORS**

Dr P K Ghosh and Sri P Narayana Murthy retire by rotation and being eligible offer themselves for re-appointment.

#### PREFERENTIAL OFFER TO THE PROMOTERS

The listing permission of 7,50,000 shares of Rs.10/each at a conversion price of Rs.80/- allotted to Dr K K Rao, promoter of the Company, on preferential basis last year is awaited from Bombay Stock Exchange.

# KEY SCIENTIFIC & ADMINISTRATIVE PERSONNEL

In line with the increased activities on R&D front several key scientific personnel have been recruited.

#### **FIXED DEPOSITS**

The company has not accepted any Fixed Deposits and the provisions of section 58A of the Companies Act, 1956 are not applicable to the Company.

#### **AUDITORS**

*M*/s Sarath & Associates, Chartered Accounts, the statutory Auditors of the Company retire at the ensuing Annual General Meeting and are eligible for reappointment.

#### **DIRECTORS' RESPONSIBILITY STATEMENT**

As required under the Companies Act, 1956, your Directors wish to state:

- a) That in the preparation of the annual accounts, the applicable Accounting standards have been followed.
- b) That the Directors had selected such accounting policies and applied them consistently and made judgments and estimates that were reasonable and prudent so as to give a true and fair view of the state of affairs of the Company at the end of the financial year and of the profit or loss of the Company for the year under review;

#### NINETEENTH ANNUAL REPORT 2009-10

- c) That the Directors had 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; and
- d) That the Directors had prepared the accounts for the year ended 31st March, 2010 on a 'going concern' basis.

#### **CORPORATE GOVERNANCE**

As required by Clause 49 of the Listing Agreement with the Stock Exchanges, your Company believes in conducting the business with due compliance of all the applicable laws, rules and regulations. The Company has duly implemented the system of Corporate Governance as per the requirement of the said Listing Agreement. Report on Corporate Governance along with Compliance Certificate of the Auditors and Management Discussion and Analysis Report are annexed hereto.

#### **EMPLOYEE RELATIONS**

Your Directors wish to express their sincere appreciation of the efficient services rendered by the employees at all levels of the company for their excellent support and contribution at all times.

There is no employee whose particulars are to be furnished pursuant to the provisions under Section 217 (2A) of the Companies Act, 1956 read with

the Companies (Particulars of Employees) Rules, 1975 as amended by the Companies (Amendment) Act, 1988.

# CONSERVATION OF ENERGY, TECHNOLOGY ABSORPTION AND FOREIGN EXCHANGE

A. Conservation of Energy, Power:

Efforts for conservation of energy and fuel consumption is an ongoing process in the Company and every effort is made in that direction.

B. Research & Development:

The Company's R&D division is recognized and certified under DSIR guidelines. Continuous efforts are being made to optimize and streamline various developmental and commercial processes.

C. Foreign Exchange Earnings: Nil

D. Foreign Exchange Outgo: Nil

#### **ACKNOWLEDGEMENTS**

Your Directors wish to place on record their gratitude to the Government authorities, for the support and co-operation received from M/S Union Bank of India, Bankers of the company, Shareholders, Auditors, Customers, vendors, business associates and Staff of the Company for their valued support during the year under review.

By the Order of the Board For **Transgene Biotek Limited** 

Sd/-

Dr.K.Koteswara Rao Chairman & Managing Director

Place: Hyderabad Date: 05.09.2010

### **Management Discussion & Analysis**

# A. Industry structure and development - Oncology

In industries populated by entrepreneurial high technology firms, the rapid development of new products is viewed as a key determinant of success. Developing a portfolio of new products is necessary to gain early cash flows, external visibility and legitimacy, early market share, and increase the likelihood of survival (Schoonhoven, Eisenhardt, and Lymman 1990).

The process of developing a new drug to treat an illness is long, costly and uncertain. A number of studies have tried to estimate the cost, the most quoted figures being those from the US Pharmaceutical Manufacturers Association (PhRMA) which are based on work done by DiMasi and others at the Tufts Center in Boston. Recent estimates by DiMasi put the average cost at US\$802 million spread over 12 years from the initial research stage to the successful marketing of a new drug, while the Boston Consulting Group estimates the cost as \$880 million over 15 years.

There are many challenges in cancer drug development, not least of which are regulatory hurdles, time consuming, risky and expensive clinical trials, basic research, biomarker development and many others. For many of us, the challenges of how to think outside the box and speed up development while treating earlier stage of disease more effectively has occupied many thoughts. Sometimes the bureaucracy across so many functions is just mind boggling.

Pharma companies have historically pursued drug discovery and development on their own, bearing all the risk and reaping all the rewards-but that model is increasingly unsustainable. The cost of developing drugs

is rising, and this, combined with a perceived decrease in the productivity of R&D, has been the one of the major reasons for the mergers and acquisitions among pharmaceutical companies over recent years, as they seek to find and exploit economies of both scale and scope in drug R&D. Oncology, an area where seemingly every company now wants to compete but where few yet possess a comprehensive expertise, is particularly ripe for such collaboration.

Oncology is the latest disease area where these trends of collaboration are increasingly apparent. While the number of patients is smaller in oncology than most primary care segments, many pharma companies have been attracted to the same opportunities due to several reasons: smaller commercial investment requirements, significantly higher prices for oncology drugs, payers who are willing to pay these prices, and a rapidly growing set of potential new drugs. The number of preclinical and clinical oncology compounds in pipelines is two to three times that of the next largest disease area. In the last five years, Pfizer has increased its oncology R&D projects by 400%, created a specialist oncology business unit, and now has more than 20 oncology compounds under various stages of development.

If done right, collaborative development will help the pharma industry in several ways. First and foremost, it will help eliminate duplicate investment by consolidating pipelines of different companies into a smaller number of broader product portfolios. To be sure, there will still be the need to develop multiple products to service niches-in areas like breast cancer, depression and schizophrenia different products are required for different genetic make-ups.

This new model could create more winners

#### NINETEENTH ANNUAL REPORT 2009-10

and fewer losers in a pharmaceutical industry currently facing an uncertain outlook. If implemented thoughtfully, the model is capable of reducing total R&D investment in the near term without compromising the development of drugs in the long term. Still, some may worry that this model will result in less innovation if pharma companies don't conduct R&D independently of each other.

# B. INTERNAL CONTROL SYSTEMS AND THEIR ADEQUACY

Your company has adequate and proper system of internal control. Your company also ensures that transactions are authorized, recorded and reported correctly.

# C. DEVELOPMENT OF HUMAN RESOURCES AND INDUSTRIAL RELATIONS

Adequate facilities and opportunities are being provided to all the staff to update themselves in the changing business environment at the company and also in relation to the clients from the countries the company is preparing to export its products.

#### D. NOTE OF CAUTION

The report provided herein on the Management Discussion and Analysis detailing the company's performance, objectives, projections, estimates and expectations may contain forward looking statements within the meaning of applicable laws and regulations. These statements are based on certain assumptions and expectations of future events. The actual results may differ substantially or materially from those expressed or implied. The company assumes no responsibility to publicity, amend, modify or revise any forward working statements, on the basis of subsequent developments, information or events.

- x x x x x x x x -

### **Corporate Governance Report**

#### 1. COMPANY'S PHILOSOPHY ON CORPORATE GOVERNANCE

The Company continues to make efforts on enhancing the value and protect the interests of its stakeholders, customers, employees, Banks, Government Agencies, etc. Conscientious of this, the company has always been formulating its business plans to mitigate and avoid any risks.

#### 2. BOARD OF DIRECTORS

The constitution of the Board is given below:

No.	Name of the Director	Status	No. of Other Public Directorships(*)	No. of Memberships on Board Committee
1.	Dr. K Koteswara Rao	Chairman & Managing Director, Promoter	NIL	2
2.	Sri P Narayana Murthy	Executive	NIL	2
3.	Sri S S Marthi	Independent	2	2
4.	Dr. P K Ghosh	Independent	2	1

<sup>(\*)</sup> This excludes Directorships in Indian Private Limited Companies, membership of Managing Committees of various Chambers/bodies.

#### 3. AUDIT COMMITTEE

An Audit Committee of the Company was constituted at the meeting of the Board of Directors held on 31st July 2002 comprising of three Directors viz., Dr K Koteswara Rao, Sri S S Marthi, and Sri P Narayana Murthy. The company is in the process of reconstituting the committee based on the corporate governance norms.

#### **TERMS OF REFERENCE**

The terms of reference of the Audit Committee includes:

- To review the internal control systems
- To review Quarterly and Half-yearly results
- To review the accounting and financial policies and practices
- To review reports furnished by the internal and statutory auditors, and ensure that suitable follow-up action is taken.

During the financial year ended 31st March 2010, 5 (Five) meetings of the Committee were held on 30th April 2009, 31st July 2009, 31st October 2009, and 30th January 2010. The attendance of each member of the Committee is given below:

Name of the Director	No. of Meetings Attended		
Dr. K. Koteswara Rao	5		
Sri S S Marthi	5		
Sri P Narayana Murthy	5		

#### 4. SHARE TRANSFER COMMITTEE

The Share Transfer Committee comprising of Dr K Koteswara Rao, Mr P Narayana Murthy, and Mr S S Marthi have been assigned the work for redressal of investor / Shareholder complaints along with approval of share transfer, sub-division/consolidation of shares, etc. The Committee oversees the performance of Registrar and Share Transfer Agents and recommends measures for overall improvement of the quality of investor services. The Share Transfers/Transmissions approved by the committee are placed at the Board Meeting from time to time.

#### **COMPLIANCE OFFICER**

Mr. N Durga Prasad, Finance Manager is the Compliance Officer of the company.

#### 5. REMUNERATION OF DIRECTORS

The details of remuneration paid to Directors are given below:

Name of the Director	Relationship with other Directors	Sitting Fee & Incidental Expenses (Rs.)	Salary & Perk (Rs.)	Total (Rs.)
Dr. K Koteswara Rao	None		8,40,000/-	8,40,000/-
Sri S S Marthi	None	2,000/-		2,000/-
Sri P Narayana Murthy	None	2,000/-		2,000/-
Dr. P K Ghosh	None	2,000/-		

#### BOARD MEETINGS AND ATTENDANCE AT BOARD MEETINGS & ANNUAL GENERAL MEETINGS

The Board of Directors of the company met 6(SIX) times during the last financial year i.e., 30th April 2009, 31st July 2009, 5th September 2009, 31st October 2009, 30th January 2010, and 25th March 2010. The company placed before the Board the annual operating plans and budgets and performance of the company from time to time. Information, which is materially important were placed before the Board Meeting as and when the same takes place.