24<sup>th</sup> Annual Report 2013 - 2014

# Reaching out to New Horizons



TRANSGENE BIOTEK LIMITED INNOVATING FOR LIFE

BOARD OF DIRECTORS				
Dr. K. Koteswara Rao	Chairman & Managing Director			
Dr. P. K. Ghosh	Director			
Sri S S Marthi	Director			

#### **Registered Office**

Plot Nos. 68,69 & 70 anrich Industrial Area, IDA Bollaram, Medak District. T.S.

#### Factory

Plot Nos. 68,69 & 70 Anrich Industrial Area, IDA Bollaram, Medak District. T.S.

#### Auditors

Sarath & Associates Chartered Accountants 4th Floor, Mass Heights, H.No. 8-2-577/B, Road No. 8 Banjara Hills, Hyderabad - 500 034

#### Bankers

**Union Bank of India** Jubilee Hills Branch, Hyderabad.

Share Transfer Agents

**M/S Bigshare Services Pvt. Ltd.** 306, 3rd Floor, Right Wing, Amrutha Ville, Bhavan Road, Somajiguda, Hyderabad - 500 082.



#### NOTICE

Notice is hereby given that the Twenty Fourth Annual General Meeting of the Members of M/S TRANSGESNE BIOTEK LIMITED will be held on Wednesday, the 31st December, 2014 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, 2014, the Profit and Loss Account for the year ended as on that date, Directors' Report and Auditors' Report thereon.

#### 2. 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 Gopal & Rajan, Chartered Accountants, be and are hereby 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 the 27th Annual General Meeting of the Company at a remuneration to be fixed by the Board of Directors in consultation with the Auditors in the place of retiring auditors M/ s Sarath & Associates, who retire by rotation and does not offer themselves for reappointment."

#### SPECIAL BUSINESS :

#### 3. APPOINTMENT OF DIRECTOR

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

"RESOLVED THAT pursuant to the provisions

of Section 149 and 152 and all other applicable provisions of the Companies Act, 2013, Companies (Appointment and Qualification of Directors) Rules, 2014 (including any statutory modification(s) or re-enactment thereof for the time being in force) Mr.Sarang Subhash Puranik be and is hereby appointed as a Director and in respect of whom the Company has received a notice under Section 160 of the Companies Act, 2013, from a member proposing his candidature for the office of Director liable to retire by rotation to hold office up to the conclusion of the 25th AGM of the Company.

#### 4. APPOINTMENT OF DIRECTOR

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

"RESOLVED THAT pursuant to the provisions of Section 149 and 152 and all other applicable provisions of the Companies Act, 2013, Companies (Appointment and Qualification of Directors) Rules, 2014 (including any statutory modification(s) or re-enactment thereof for the time being in force) Mr. Shyam Shankar Das be and is hereby appointed as a Director and in respect of whom the Company has received a notice under Section 160 of the Companies Act, 2013, from a member proposing his candidature for the office of Director Iiable to retire by rotation to hold office up to the conclusion of the 25th AGM of the Company.

> By the Order Of the Board For **TRANSGENE BIOTEK LIMITED**

PLACE: HYDERABAD DATE: 06.12.2014 Sd/-Dr. K. KOTESWARA RAO CHAIRMAN & MANAGING DIRECTOR

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## NOTES :

- 1. A MEMBER ENTITLED TO ATTEND AND VOTE AT THE MEETING IS ENTITLED TO APPOINT A PROXY TO ATTEND AND VOTE INSTEAD OF HIMSELF AND SUCH PROXY NEED NOT BE A MEMBER OF THE COMPANY. THE PROXIES TO BE EFFECTIVE SHOULD BE DEPOSITED AT THE REGISTERED OFFICE OF THE COMPANY NOT LATER THAN 48 HOURS BEFORE THE COMMENCEMENT OF THE MEETING.
- 2. The relevant details of the directors seeking appointment under Item Nos, 3 and 4 above, as required by Clause 49 of the Listing Agreement entered into with the Stock Exchange are annexed.
- 3. Register of members and share transfer books of the company will remain closed from 29-12-2014 to 31-12-2014 (both days inclusive). Members/Proxies should bring the attendance slips duly filled in and signed for attending the meeting.
- 4. As per the provisions of the Companies Act, 2013, facility for making nomination is available for Members of the Company in respect of shares held by them. The members, who wish to nominate a person, may furnish the required details to the Company in prescribed form.
- 5. The Ministry of Corporate Affairs has taken a "Green Initiative in the Corporate Governance" by allowing paperless compliances by the companies and has issued circulars stating that service of notice/documents including Annual Report can be sent by e-mail to its members. To support this green initiative of the Government in full measure, members who have not registered their e-mail addresses, so far, are requested to register their e-mail addresses. In respect of electronic holdings, with the

Depository through their concerned Depository Participants and members who hold shares in physical form are requested to register the same with our RTA, Bigshare Services Pvt Ltd, 306, Right Wing, Amruta Ville, Opp Yashoda Hospital, Raj Bhavan Road, Somajiguda, Hyderabad 500082.

# 6. VOTING THROUGH ELECTRONIC MEANS

In compliance with the provisions of the Clause - 35B of the Listing Agreement read with Section 108 of the Companies Act. 2013 and the Rule 20 of the Companies (Management and Administration) Rules, 2014, the company is pleased to provide members facility to exercise their votes for all the resolutions detailed in the Notice of the 24th Annual Report of the company and the business may be transacted through e-voting. The company has engaged the services of Central Depository Services Limited (CDSL) as the authorized agency to provide the e-voting facility.

The instructions for shareholders voting electronically are as under:

Mr. M V R Murthy (Membership No.ACS.21661) Practising Company Secretary, is appointed as scrutinizer to conduct E-voting.

## STEPS FOR E-VOTING

 (i) The voting period begins on 26th December, 2014 at 9.00 a.m. and ends on 27th December, 2014 at 6.00 P.M. During this period shareholders' of the Company, holding shares either in physical form or in dematerialized form, as on the cut-off date (record date) of 28th November, 2014, may cast their vote electronically. The e-voting module shall be disabled by CDSL for voting thereafter.



- (ii) The voting rights of members shall be in proportion to their shares of the paid up equity share capital of the company as on 28th November, 2014.
- (iii) The shareholders should log on to the evoting website www.evotingindia.com.
- (iv) Click on Shareholders.
- (v) Now enter your User ID:
  - a. For CDSL: 16 digits beneficiary ID,
  - b. For NSDL: 8 Character DP ID followed by 8 Digits Client ID,
  - c. Members holding shares in Physical Form should enter Folio Number registered with the Company.
- (vi) Next enter the image verification as displayed and Click on Login.
- (vii) If you are holding shares in demat form and had logged on to www.evotingindia.com and voted on an earlier voting of any company, then your existing password is to be used.
- (viii) If you are a first time user follow the steps given below :

	For Members holding shares in Demat Form and Physical Form		
	Enter your 10 digit alpha-numeric PAN issued by Income Tax Department		
	(Applicable for both demat shareholders as well as physical shareholders)		
PAN	Members who have not updated their PAN with the Company/ Depository Participant are requested to use the first two letters of their name and the 8 digits of the sequence number in the PAN field.		
	• In case the sequence number is		

	less than 8 digits enter the applicable number of 0's before the number after the first two characters of the name in CAPITAL letters. Eg. If your name is Ramesh Kumar with sequence number 1 then enter RA00000001 in the PAN field.		
DOB	Enter the Date of Birth as recorded in your demat account or in the company records for the said demat account or folio in dd/mm/yyyy format.		
Dividend	Enter the Dividend Bank Details as recorded in your demat account or in the		
Dividend Bank Details	Company records for the said demat account or folio.		
	<ul> <li>Please enter the DOB or Dividend Bank Details in order to login. If the details are not recorded with the depository or company please enter the member id / folio number in the Dividend Bank details field as mentioned in instruction (v).</li> </ul>		

- ix) After entering these details appropriately, click on "SUBMIT" tab.
- Members holding shares in physical form (X) will then directly reach the Company selection screen. However, members holding shares in demat form will now reach 'Password Creation' menu wherein they are required to mandatorily enter their login password in the new password field. Kindly note that this password is to be also used by the demat holders for voting for resolutions of any other company on which they are eligible to vote, provided that company opts for evoting through CDSL platform. It is strongly recommended not to share your password with any other person and take utmost care to keep your password confidential.

- (xi) For Members holding shares in physical form, the details can be used only for e-voting on the resolutions contained in this Notice.
- (xii) Click on the EVSN for the relevant TRANSGENE BIOTEK LIMITED on which you choose to vote.
- (xiii) On the voting page, you will see "RESOLUTION DESCRIPTION" and against the same the option "YES/NO" for voting. Select the option YES or NO as desired. The option YES implies that you assent to the Resolution and option NO implies that you dissent to the Resolution.
- (xiv) Click on the "RESOLUTIONS FILE LINK" if you wish to view the entire Resolution details.
- (xv) After selecting the resolution you have decided to vote on, click on "SUBMIT". A confirmation box will be displayed. If you wish to confirm your vote, click on "OK", else to change your vote, click on "CANCEL" and accordingly modify your vote.
- (xvi) Once you "CONFIRM" your vote on the resolution, you will not be allowed to modify your vote.
- (xvii) You can also take out print of the voting done by you by clicking on "Click here to print "option on the Voting page.
- (xviii) If Demat account holder has forgotten the same password then Enter the User ID and the image verification code and click on Forgot Password & enter the details as prompted by the system.

- (xix) Note for Non-Individual Shareholders & Custodians:
  - Non-Individual shareholders (i.e. other than Individuals, HUF, NRI etc.) and Custodians are required to log on to www.evotingindia.com and register themselves as Corporates and Custodians respectively.
  - A scanned copy of the Registration Form bearing the stamp and sign of the entity should be emailed to helpdesk.evoting@cdslindia.com.
  - After receiving the login details they have to create a compliance user should be created using the admin login and password. The Compliance user would be able to link the account(s) for which they wish to vote on.
  - A scanned copy of the Board Resolution and Power of Attorney (POA) which they have issued in favour of the Custodian, if any, should be uploaded in PDF format in the system for the scrutinizer to verify the same.
- (xx) In case you have any queries or issues regarding e-voting, you may refer the Frequently Asked Questions ("FAQs") and e-voting manual available at www.evotingindia.com under help section or write an email to

helpdesk.evoting@cdslindia.com.



Information required to be furnished under clause 49 of the listing agreement for directors seeking appointment/reappointment in forthcoming annual general meeting:

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Name of Director	Mr.Sarang Subhash Puranik	
Date of Birth	30/07/1979	
Date of Appointment	31/12/2014	
Qualification	PhD	
Expertise Microbiology, Immunology & Nanol		
Other directorship	None	
Chairman/Members of the Committee in other Companies	None	
No of shares held in the Company	None	
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Name of Director	r Mr.Shyam Shankar Das	
Date of Birth	05/10/1968	
Date of Appointment	31/12/2014	
Qualification	M.Tech	
Expertise	Fermentation based Bio-technology	
Other directorship	None	
Chairman/Members of the Committee in other Companies	None	
No of shares held in the Company	None	

#### EXPLANATORY STATEMENT PURSUANT TO SECTION 102 OF THE COMPANIES ACT, 2013.

### ITEM NO. 1

Mr. Sarang Subhash Puranik, is proposed to be appointed as Director of the company liable to retire by rotation. The company has received a notice from the member proposing his candidature for appointment as Director of the company.

None of the Directors other than Mr. Sarang Subhash Puranik himself is concerned or interested in the proposed resolution.

### **ITEM NO.2**

Mr. Shyam Shankar Das, is proposed to be appointed as Director of the company liable to retire by rotation. The company has received a notice from the member proposing his candidature for appointment as Director of the company.

None of the Directors other than Mr. Shyam Shankar Das himself is concerned or interested in the proposed resolution.

> By the Order Of the Board For **TRANSGENE BIOTEK LIMITED**

PLACE: HYDERABAD	
DATE: 06.12.2014	

Sd/-Dr. K. KOTESWARA RAO CHAIRMAN & MANAGING DIRECTOR

## **DIRECTORS REPORT**

Dear Shareholders,

Your Directors invite you to the 24th Annual Report on the business & operations of the company and Audited Statement of Accounts for the year ended 31st March, 2014 along with the Auditor's Report thereon.

## **Financial Results :**

	(Rs. in Lakhs)		
Particulars	2013-20142012- 2013		
Total Income	181.31	1509.00	
Operational, Administratio	n		
and other expenses	278.82	1590.95	
Gross Operating Profit	(99.51)	(81.95)	
Interest and Financial Cha	arges 0.05	19.98	
Forex Gain/Loss	0.00	0.00	
Depreciation	1721.55	101.51	
Profit before Tax/Loss	(1821.11)	(203.44)	
Extraordinary Items	11522.13	0.00	
Provision for Tax	0.00	0.00	
Net Profit	(13341.24)	(203.44)	

## Review and results of operations

As informed earlier, we have started the production of first of a series of biogenerics at the purpose built cGMP compliant biologics manufacturing facility at our partner's plant in our vicinity.

Now coming to the operations of your company, this year also signifies several new changes to your company at the board level, administrative and managerial levels. This new and emerging structure makes your company more functional than at any time in the past since its inception in 1991.

A noteworthy aspect in this emerging structure is the new Board of Directors to be elected to be approved by the shareholders. Your company is now embarking on a new direction that hopefully leads to the long expected results that are eluding all these years. As a part of the emerging scenario, the outgoing Board and management have segmented the product pipeline into two broad categories: Biologics and Bio-innovations. Within each category the pipeline is prioritized on the deliverability and commercial realization at the earliest.

## SEBI INTERIM ORDER :

Securities & Exchange Board of India (SEBI) vide its Interim Order No. WTM/RKA/ISD/136/ 2014 dated November 20, 2014 had made certain comments in the matter pertaining to the funds raised in the GDR Issue of the Company and inter alia, refrained, the Company from issuing securities.

We wish to place before the shareholders that Order has been passed without giving the Company or its Directors an opportunity of being heard. The Board has decided to contest the said Order of SEBI at the appropriate forum. As regards the amounts involved, as stated above, the Company is taking steps to independently evaluate the matter and would initiate efforts to protect the interests of all the shareholders.

## AUDITORS' COMMENTS

As regarding comments of the Auditors under "Emphasis of Matter" the replies of the Management are as under:-

 As regards their comment on the Investments made in the Wholly Owned subsidiary company is concerned, it is stated that due to the resignation of M/s Anchorman Limited as the Director of the Company with effect from 24.9.2013 without informing the Indian Parent Company, there is no one to look after the affairs and now Mr. K Koteswara Rao was appointed as Sole Director with effect from 24.11.2014. The appointed Auditor also resigned and new Auditors were appointed with effect from November 2014 and due to paucity of time, the new



Auditors could not get full evidence which resulted in they stating disclaimer of opinion. Your Directors are confident that these aspects would be suitably addressed in the coming days;

- 2) As regards their comment on the going concern aspect mentioned in para No.2, your Board reiterate the stand/course of action mentioned above and are confident that the order of SEBI will have no impact on the Company as a going concern.
- As regards their comment in para No.3, the Board is in the process of taking Expert's Opinion and appropriate course of action;
- As regards their comment in para No.4, the Board is of view that the amounts stated therein are fully recoverable and Board had already initiated appropriate process.

As regards comments of the Auditors under "Report on other Legal and Regulatory requirements" under various clauses, your Directors had already initiated the process of strengthening the systems and procedures and also assure the shareholders that they will take all the steps which are necessary for protecting the interests of all the shareholders.

The comments of the Auditors in respect of Technology are self-explanatory read with the Notes to the Schedule of Fixed Assets.

### BIOLOGICS

As stated above, your management wishes to focus on deliverables as a priority, hence wishes to commercialise each biological product in series after stabilization of production and marketing of each product.

The three biologics in the pipeline are DHA, Orlistat and Tacrolimus as informed previously.

**DHA** : As reported regularly during the quarterly results, your company entered into a Manufacturing and Marketing agreement with a pharmaceutical intermediates manufacturing and marketing company, Rampex Labs Pvt Ltd, located in the same industrial estate as your company Transgene Biotek Ltd.

Rampex Labs Pvt Ltd is a pharmaceuticals intermediates manufacturing company with a marketing prowess to various parts within and outside India.

Rampex has constructed a purpose built cGMP compliant Biologics manufacturing facility for the purpose of manufacturing and marketing the biologics developed by your company. Transgene granted an exclusive non-transferable license to Rampex for Transgene to transfer its technology for the manufacture and commercialization of DHA using the scientists of Transgene for the production. The period of license is for 10 years.

With the plant being new and purpose built for the production of biological, the management of your company hopes to utilize that facility for additional biologics once the DHA production and commercialization is stabilized. The management also expects Rampex to get the cGMP certification for DHA production for its entry into regulated markets that provides significant value addition although the management expects stiff resistance from the global majors in those markets.

**ORLISTAT**: Since the earlier agreement with DRL did not turn out to be a mutually beneficial relationship, this product with its technology is to be handed back to your company for it likely to be produced at the new Rampex plant once the path is clear.

**TACROLIMUS**: The agreement with Atral Cipan of Portugal has been terminated because of inordinate delay in commercial production of this product. The management is exploring for a similar arrangement with another pharmaceutical company for the manufacturing and commercialization of this product as in the case of DHA.

## **BIO-INNOVATIONS**

TrabiOralTM - An innovative technology for delivery of protein and peptide drugs through oral route

TrabORINTM - Oral Delivery of Insulin

TrabORINTM is a proprietary encapsulated formulation that effectively and efficiently delivers the required dosage of insulin into the bloodstream, in a sustained release that avoids the 'crests and troughs' profile of blood glucose levels that many diabetic patients suffer from via subcutaneous insulin injections. TrabORINTM, which has the capacity to deliver large quantities (dosages) of insulin has demonstrated a very effective reduction of blood-glucose levels in two different strains of rats in a series of blind studies. These results highlight the ability of the TrabORINTM delivery technology to cross the GI barrier and deliver insulin into systemic blood circulation.

# TrabiORAL<sup>™</sup> - Oral delivery of protein and peptide drugs

TrabiORALTM technology combines several novel inventions to produce an orally active transport system (mostly) for protein and peptide drugs. It employs TBL's proprietary conjugation technology and patentedencapsulation technology for amplification of the uptake mechanism in the GI tract resisting drug proteolysis. It's versatility has revealed an ability to deliver a variety of Protein and Peptide based drugs, from small molecules (e.g. 6kDa insulin) to larger molecules (e.g. 150kDa mAbs). TrabiORAL<sup>™</sup> hence offers a tailored approach for each individual drug.

There is an ongoing dialogue with different pharma companies for out-licensing these technologies. In case of TrabiORINTM several new studies have been conducted during the last year to demonstrate its unique mechanism of action and bioavailability in strengthening our defense during the ongoing dialogue.

## ONCOLOGY

TBL-0306 - A novel monoclonal antibody drug

As reported last year, TBL-0306 a monoclonal antibody drug has been undergoing various studies. However, as a new initiative in restructuring the company's operations for improved functionality, the management wishes to focus on one clinical oncology drug at a time advancing it to the next critical milestone before on to moving to the next one. Therefore, TBL-0306 against Colon cancer is one of the drugs in oncology section priortised to advance before moving on to Non-Hodgkin's Lymphoma and Multiple Myeloma. Likewise, the second mAb against Oesophageal cancer also has been put on hold.

## RNAi DRUGS

Like in the case monoclonal antibody drugs, the list of RNAi drugs also have been priortised.

# TBL-0404 Liver Cancer Drug

TBL-0404 against Liver cancer is a new generation complex and highly advanced oncology drug employing tissue specific miRNA delivered through Transgene's patented and proprietary AAV genetically modified delivery system.TBL-0404 is advancing well with optimized transfection efficiency and improved purification protocol in order to produce the drug in larger quantities in preparation for the in-vivo studies.

# TBL-0905 Breast Cancer Drug

As mentioned above, the management in its restructuring strategy plans to advance one drug in each category for optimal utilization and for better focus before moving on to the next in that section of the drug development pipeline. Accordingly, TBL-0905 against Breast cancer