



TBG Diagnostics Limited

2016 AGM Presentation

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An emerging leader in Molecular Diagnostics.

TBG Diagnostics is a global molecular diagnostic (MDx) company operating in the IVD (in vitro diagnostics) industry. We are focused on the development, manufacture and marketing of molecular diagnostic kits, instruments and services.



Our Vision

To capitalise on our proven history, expertise and current footprint in China

To become one of the leading molecular diagnostics solutions providers in the Asia Pacific region



Growth Strategy

Focus on molecular diagnostics business

- ASX listing on Feb 6th 2016 and board and management appointments
- Sale of Pharmasynth Pty Ltd to LuinaBio Pty Ltd
- Sale of PG500 to Zucero Therapeutics Pty Ltd

Focus on China – the fastest growing market in the world

- Total share of world market: 4.5% in 2013 to 14.7% in 2024 (market value of USD \$3.46Bn)
- TBG Plant production in China as government favors locally manufactured products
- Product development aims for registration with CFDA

Focus on products with automation

- Automation to increase accuracy and efficiency
- Offer superior quality products to Asia Pacific market
- Development of a new fully automated molecular diagnostic system

Focus on high growth by M&A and building partnerships

- Key components to enhance TBG's overall competitiveness
- Innovative MDx products based on TBG's platforms
- Due diligence with RBC to acquire 51% of equity stake

Current Business. We serve blood transfusion and transplantation market with the following products:

**ExProbe™
HPA Kits**



Designed for HPA alleles using real time PCR techniques with sequence specific primers and probes

**HLAssure™
SBT
HLA Kits**



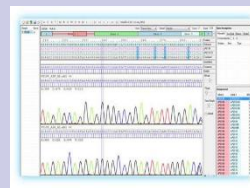
High resolution typing of HLA alleles using PCR techniques with sequence based typing

**Morgan™
SSP
HLA Kits**



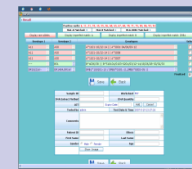
Designed for determining HLA alleles using PCR techniques with sequence specific primers (SSP)

**AccuType™
Software**



Data analysis software used specifically to translate high throughput screening results

**SSPal™
Software**



Gel analysis software. Interprets Morgan™ HLA SSP Typing Kits

**Halotype™
NGS**



High resolution genotyping using combination Assay and Software with NGS

2016 Highlights

Blood Transfusion and Transplantation Business

- Sales:
 - 33% sales growth from NT\$43.7m to NT\$58.3m (AUD2.48m) for period from 1/1/2016 to 30/9/2016
 - Placed initial sales order of HLA Kit with Leading US Cancer Treatment Centre MD Anderson, University of Texas
 - Commenced sales into Russia with HLA SBT for research use
 - HLA typing service commenced in China with first revenue
 - Using TBG SSP Typing kits, Iranian customer will publish the largest HLA frequency study for the Iranian population and become the new gold standard for clinical labs
 - ExProbe™ HPA Typing Kit won the Singapore government tender for the establishment of the National HPA Databank

2016 Highlights

Blood Transfusion and Transplantation Business

- Product Approval:
 - Received Taiwan DOH approval for B27 qPCR typing Kit (a test for Ankylosing Spondylitis) in Oct 2016
 - HLAAssure SBT kits passed first phase CFDA review. Additional 200 leukemia patient samples were requested to be included in the trial. Will be the first HLA SBT product to receive approval in China if approved by CFDA
- Product Development:
 - Completed verification of HLA RTPCR design, validation in process
- Product Distribution:
 - Received Exclusive Distributorship of Omixon HLA NGS for China, Hong Kong, Taiwan, and Australia
- Grants:
 - CNY 300,000 (approximately AUD 64,000) grant from Xiamen Municipal Technology Bureau for HLA Typing Kit Development

2016 Highlights

New MDx Business to focus on the China market

- Facility:
 - Established manufacturing capabilities certified by ISO 13485 in Xiamen China
- Product Approval:
 - Cleared CFDA for whole blood nucleic acid extraction kit
- Product Development:
 - Completed design verification for 3 oncology drug companion tests and two infectious disease viral load tests
 - Validation of TBG RTPCR instrument expected to complete by end of year

2017 Commercial Goals

Blood Transfusion and Transplantation Business

- Sales:
 - To surpass NT\$100m (AUD4.25m) in sales
- Product Approval:
 - To gain HLAssure SBT product registration in Russia and China
 - To gain HLA RTPCR product registration for Europe (CE) and Taiwan
 - To complete HLA RTPCR clinical trials and submit for CFDA approval in China
- Product development:
 - To expand product pipeline including RBC typing
- Accreditation:
 - Xiamen service lab to obtain ASHI accreditation and become TBG's second ASHI accredited lab
- Production:
 - Extend HLA SSP CE production line from Taiwan to Xiamen to meet increased demand

2017 Commercial Goals

New MDx Business to focus on the China market

- Product Approval:
 - To complete 4 infectious disease clinical trials and submit for CFDA registration
 - Complete validation of 4 infectious disease products and begin clinical trials
 - Obtain CE mark and Taiwan DOH approval for RTPCR instrument
- Product Development:
 - To complete validation of 4 infectious disease plus 4 prenatal/postnatal tests and prepare for clinical trials
 - To complete validation of 3 oncology companion tests
- Service Business:
 - To obtain 3rd party reference license in Xiamen

Research & Development

Several projects aimed at creating precise automated MDx systems for hospitals and commercial uses:

- Oncology
- Infectious diseases
- Transplantation
- Transfusion
- Pharmacogenetics
- Autoimmune disease
- Prenatal/Postnatal disorder

RTPCR: Ongoing Product Development

- Undertaking certification and anticipate CE mark and Taiwan regulatory approval in 2017



Integrated Automated Clinical System: Ongoing Product Development

- R&D phase, to consolidate design by 2017



Remodel the automated blood
screening system



TBG RT-PCR



Full spectrum MDx menu

Corporate Snapshot

Key Financial Details

ASX:TDL
TBG Diagnostics Limited

Market Capitalisation as at 11th November 2016

39.2M

Ordinary Shares

217,587,289

Unlisted Options

5,112,000

Cash balance as at 31st October 2016

\$11.5M

TBG Diagnostics was relisted on the ASX on 3rd February 2016 after successfully raising
\$12,721,590 **

Board and Management



Jitto Arulampalam
Executive Chairman

Currently Chairman of Lanka Graphite Ltd (ASX: LGR), formerly Chair of Fortis Mining and Great Western Exploration (ASX:GTE), Medicvision Ltd, Euro Petroleum



Eugene Cheng
Group COO, CEO of TBG
Taiwan and TBG Xiamen

President of Medigen Biotechnology Corporation, Former VP and Chief of Staff at Acer



Dr Stanley Chang
Non-executive Director

Current Chairman of Medigen Biotechnology Corporation, MD degree from National Taiwan University College of Medicine, Ph.D. degree in Laser Medicine from the University College London of London University, UK



Emily Lee
Non-executive Director

Managing Director of Lanka Graphite Limited (ASX:LGR), Founder of Mercer Capital, Innovation Expert Panel State Government of Victoria



Edward Chang
Non-executive Director

Director of Finance at Eternal Materials, former Manager of Treasury and Risk Management at Motech Industries

Contact

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