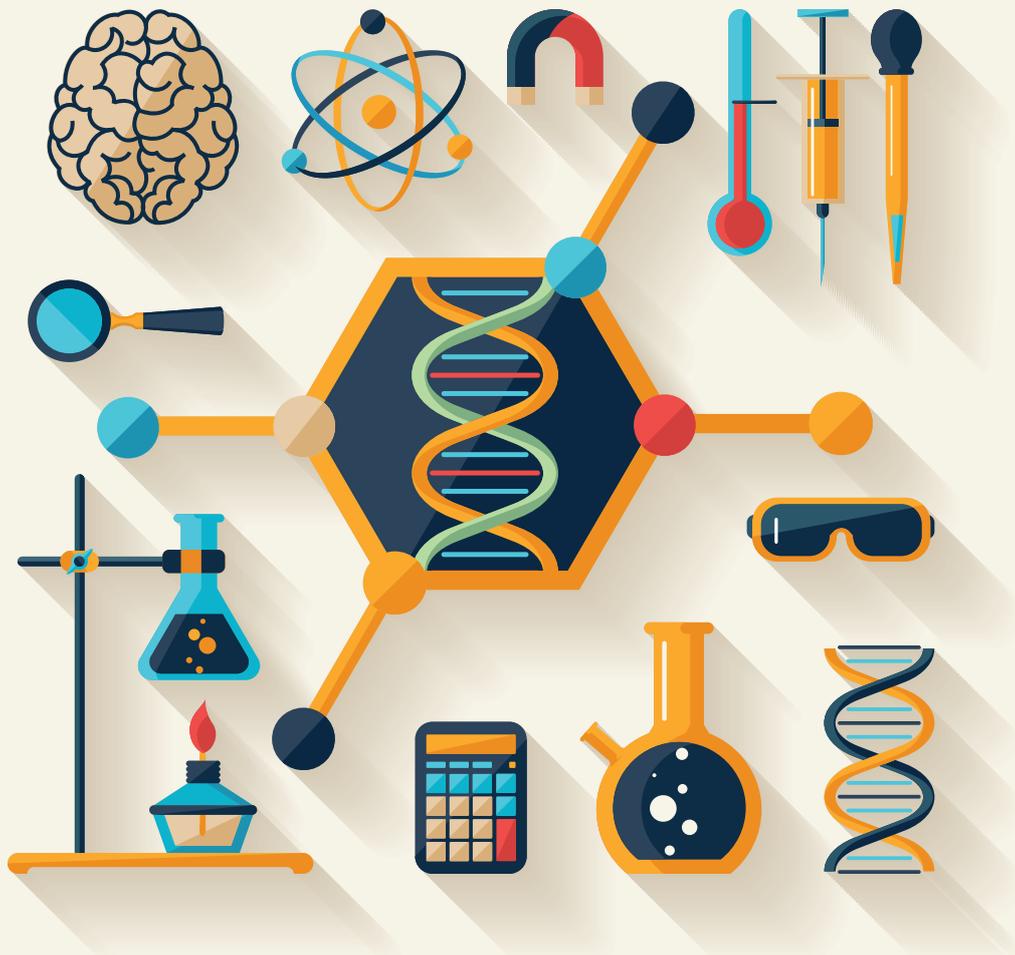




# READY TO INSPIRE

KEY PERFORMANCE HIGHLIGHTS

2013







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# ABOUT BIOTEHCORP

## Introduction

**Malaysian** Biotechnology Corporation Sdn Bhd (BiotechCorp) (Company No. 691431-D) was incorporated under provisions of the Companies Act 1965 on 13 May 2005 to identify value propositions in research, development and commercialisation (R&D&C) as well as to support and facilitate these ventures through financial assistance and advisory services.

BiotechCorp is an agency of the Ministry of Science, Technology and Innovation (MOSTI) and owned by the Ministry of Finance Incorporated and Federal Lands Commissioner.

It is governed by the National Bioeconomy Council (NBC) (formerly known as Biotechnology Implementation Council) and counselled by the Bioeconomy International Advisory Panel, both are chaired by the Honourable Prime Minister of Malaysia.

### Key Mandates

- Act as a focal point for all biotechnology initiatives in Malaysia.
- Nurture and accelerate growth of Malaysian biotechnology companies.
- Actively promote foreign direct investments in biotechnology.
- Create a conducive environment for biotechnology in Malaysia.

### Vision

To enhance the economic, health and social well being of the nation.

### Mission

Lead the development of the biotechnology industry in Malaysia.

### Corporate Values

- **Teamwork :**  
In a relationship based on mutual respect & understanding, we work together with our colleagues, clients and partners to achieve common goals.
- **Integrity :**  
We conduct our business with uncompromising integrity.
- **Excellence :**  
We strive to achieve excellence in all that we do.
- **Accountability :**  
We drive the delivery of results for the organisation and the nation.

## 2013 HIGHLIGHTS

### Key Indicators for the Biotechnology Industry

as at 31 December 2013

Indicators	Target			Phase II Achievements as of 2013
	Phase I (2005-2010)	Phase II (2011-2015)	Phase III (2016-2020)	
Investment	RM 6 Billion	RM 9 Billion	RM 15 Billion	RM 14.8 Billion
Number of BioNexus Companies	25	25	50	228
Employment	40,000	80,000	160,000	83,400
Annual Revenue	RM 20 Billion	RM 50 Billion	RM 100 Billion	RM 2.9 Billion*

\* Based on Online Submission System (OSS) reporting by BioNexus Status companies.

## FACTS & FIGURES

### BioNexus Companies

Approved Investment by Industry	Total 2012 (RM'Million)	Total 2013 (RM'Million)	Total (2005-2013) (RM'Million)
AgBiotech	783.6	614.6	2,312.7
BioIndustrial	39.4	0	513.8
BioMedical	28.3	83.1	519.0
	<b>851.3</b>	<b>697.7</b>	<b>3,345.5</b>

Realised Investment by Industry	Total 2012	Total 2013	Growth (%)
AgBiotech	1,028.9	1,113.4	8.2%
BioIndustrial	524.4	566.00	7.9%
BioMedical	936.5	948.0	1.2%
	<b>2,489.8</b>	<b>2,627.4</b>	<b>5.5%</b>

R&D Expenses by Industry	Total 2012	Total 2013	Growth (%)
AgBiotech	35.9	46.2	28.7%
BioIndustrial	7.0	7.6	8.6%
BioMedical	54.1	45.7	-15.5%
	<b>97.0</b>	<b>99.5</b>	<b>2.6%</b>

Employment by Industry	Total 2012	Total 2013	Growth (%)
AgBiotech	1,416.0	1,485.0	4.9%
BioIndustrial	643.0	653.0	1.6%
BioMedical	898.0	868.0	-3.3%
	<b>2,957.0</b>	<b>3,006.0</b>	<b>1.7%</b>

Knowledge Workers by Industry	Total 2012	Total 2013	Growth (%)
AgBiotech	577.0	619.0	7.3%
BioIndustrial	245.0	275.0	12.2%
BioMedical	548.0	540.0	-1.5%
	<b>1,370.0</b>	<b>1,434.0</b>	<b>4.7%</b>

Revenue by Industry	Total 2012	Total 2013	Growth (%)
AgBiotech	324.4	342.2	5.5%
BioIndustrial	476.0	551.7	15.9%
BioMedical	218.9	275.4	25.8%
	<b>1,019.3</b>	<b>1,169.3</b>	<b>14.7%</b>

# CALENDAR OF EVENTS

## ▶ January

7 - 9 , 2013

**JP Morgan Healthcare  
Conference**  
*San Francisco, USA*

## ▶ February

19 - 20 , 2013

**Bio Borneo 2013**  
*Sabah, Malaysia*

21 - 22 , 2013

**Bioeconomy Transformation  
Programme (BTP) Workshop**  
*Sabah, Malaysia*

## ▶ March

18 - 21 , 2013

**BioPharma Asia  
Convention 2013**  
*Singapore*

## ▶ April

22 - 25 , 2013

**BIO International  
Convention**  
*Chicago, USA*

## ▶ June

6 - 7 , 2013

**9th Malaysian International  
Agro-bio Business Conference 2013**  
*Kuala Lumpur, Malaysia*

10 - 11 , 2013

**Bioeconomy Transformation  
Programme (BTP) Workshop**  
*Sarawak, Malaysia*

12 - 14 , 2013

**2nd Biogas Asia Pacific  
Forum**  
*Kuala Lumpur, Malaysia*

16 - 19 , 2013

**10th Annual World Congress  
on Industrial Biotechnology**  
*Montreal, Canada*

25 - 26 , 2013

**Bioeconomy Investor  
Forum (BIF)**  
*Kuala Lumpur, Malaysia*

## ▶ July

15 - 18, 2013

**Asian Food and Agribusiness Conference**  
*Taipei, Taiwan*

15, 2013

**Biotechnology Entrepreneur Special Training (BeST) Programme**  
*Universiti Putra Malaysia (UPM), Malaysia*

29, 2013

**Biotechnology Entrepreneur Special Training (BeST) Programme**  
*Universiti Malaysia Perlis (UniMAP), Malaysia*

24-25, 2013

**Sarawak BTP Lab Session**  
*Kuching, Malaysia*

9, 2013

**Biotechnology Entrepreneur Special Training (BeST) Programme**  
*Universiti Malaysia Pahang (UMP), Malaysia*

22, 2013

**Biotechnology Entrepreneur Special Training (BeST) Programme**  
*AIMST University, Malaysia*

23, 2013

**Sabah BTP Lab Session**  
*Sabah, Malaysia*

## ▶ August

29 - 30, 2013

**Bioeconomy Transformation Programme (BTP) Workshop**  
*Penang, Malaysia*

## ▶ September

24, 2013

**Biotechnology International Advisory Panel (Bio-IAP)**  
*San Francisco, USA*

## ▶ September - October

30 - 2, 2013

**6th Annual European Forum for Industrial Biotechnology (EFIB)**  
*Brussels, Belgium*

## ▶ October

21 - 23, 2013

**Asia Bio Markets**  
*Johor, Malaysia*

## ▶ October

21 - 23, 2013

**BioMalaysia & Bioeconomy Asia Pacific 2013 and BioCareer & BioEducation 2013** *Johor, Malaysia*

## ▶ November

20 - 21, 2013

**Northern BTP Lab Session**  
*Penang, Malaysia*

## ▶ November

20 - 23, 2013

**Medica 2013**  
*Dusseldorf, German*

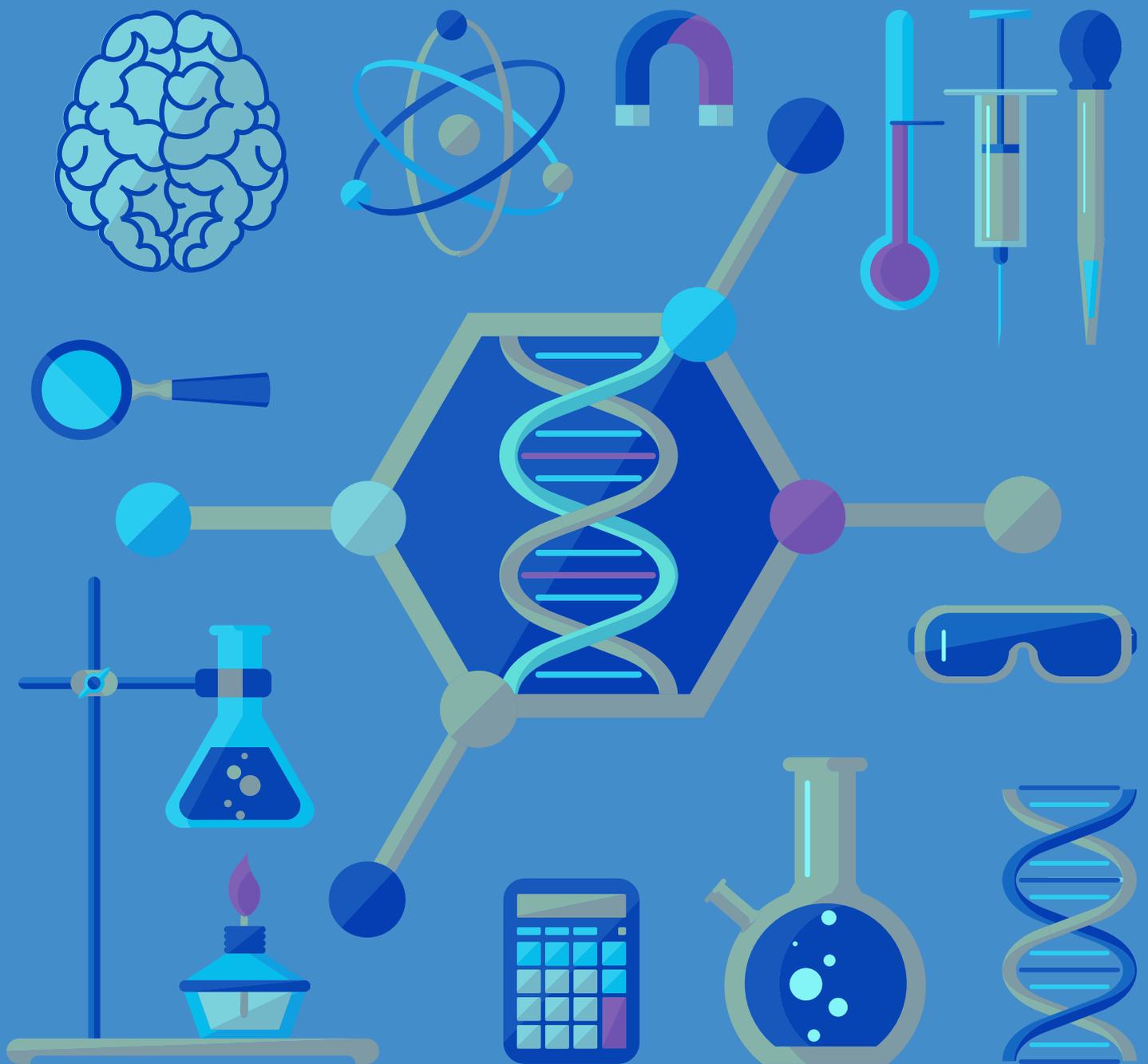
## ▶ December

3 - 5, 2013

**Malaysian Genomics Congress**  
*Putrajaya, Malaysia*

# KEY RESULTS

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## BIOECONOMY DEVELOPMENT

Bioeconomy Transformation Programme (BTP) Workshops				
LOCATION	TOTAL COMMERCIALY READY PROJECTS	AgBiotech	BioIndustrial	BioMedical
Sabah	32	15	13	4
Sarawak	14	12	2	-
Northern Region	13	7	4	2

**Projects** are identified as commercially ready based on the Technology Readiness Level (TRL) assessment system adapted from United States National Aeronautics and Space Administration (NASA) and Michigan State University Bioeconomy Institute. TRL1-6 (Stage 1) includes basic research and feasibility demonstration, TRL7-8 (Stage 2) refers to pilot scale demonstration, and TRL 9 (Stage 3) is defined as large-scale commercial operations.

	2012	2013	2020
	10 EPPs and 20 Trigger Projects	13 Pipeline Projects	Target
 GNI in 2020	RM 3.6 BILLION	RM 0.97 BILLION	RM 48 BILLION
 Job Opportunities by 2020	16,300	1,700	170,000
 Investment by 2020	RM 10 BILLION	RM 3.8 BILLION	RM 50 BILLION

## Strategic International & Domestic Partnerships

- 1 **MOU Exchange between BiotechCorp and Department of Statistics Malaysia**  
*Bio Borneo 2013, Kota Kinabalu*
  - ▶ MoU signing to enhance the quality of official statistics for bio-based industry.
- 2 **Collaboration Proposal between BiotechCorp and Michigan State University**  
*BIO-IAP 2013 Meeting, San Francisco, United States*
  - ▶ To strengthen US-Malaysia Bioeconomy business and research communities.

## Key Announcements & Events

- 1 **Global Launch of BTP**  
*BIO Chicago 2013, United States*
  - ▶ Highlight Malaysia as the second in Asia after China and the first in ASEAN, to establish its own Bioeconomy initiative.
- 2 **Announcement of the Bioeconomy Community Development Programme (BCDP) and Bioeconomy R&D Incentives** *Parliament Building, Kuala Lumpur*
  - ▶ Announced by the Prime Minister of Malaysia during the 2014 National Budget briefing.
- 3 **Announcement of BTP Fund**  
*BIO-IAP 2013 Meeting, San Francisco, United States*
  - ▶ To announce the RM85 million allocation to develop Malaysia's bioeconomy.
- 4 **Announcement of the Bioeconomy Malaysia Accelerator Programme**  
*BIO-IAP 2013 Meeting, San Francisco, United States*
  - ▶ Programme to accelerate bioeconomy development involving stakeholder collaborations with the Economic Corridors, universities, research institutions, finance institutions and inter-ministerial agencies.
- 5 **Launch of the California Institute for Quantitative Biosciences (QB3) Malaysian Bio-entrepreneurship Accelerator Programme**  
*BIO-IAP 2013 Meeting, San Francisco, United States*
  - ▶ One of the implementation strategies to create a conducive environment for Malaysian businesses to become global in scale and skill.
- 6 **Launch of the BTP 2013 Annual Report**  
*BioMalaysia 2013, Johor*
  - ▶ The annual report aims to provide the public and private sectors with an overview of the current status and progress of the BTP in 2013 as well as its future plans.
- 7 **Activities with Consortium Libraries**
  - ▶ Exchange of books between RC and Petronas Resource Centre for a period of three months. Books can be borrowed and used as reference within this period.
- 8 **Get to Know RC**
  - ▶ Sessions arranged for new comers and members to explore RC collections and services. The session is to encourage usage via RC's website and enhance searching capabilities using databases subscribed by RC for maximum use of news and information in performing daily work.
- 9 **Bookfair@RC**
  - ▶ Two-day book fair organized on the 22 and 23 July 2013, showcasing a wide range of subjects with an aim to provide a platform for internal and external members in selecting items for BRC collection and also for the members to expand their own personal book collection.

## BUSINESS DEVELOPMENT & INVESTMENT

### AgBiotech



### Investment

▶ **Approved investments:**  
**RM919.3** MILLION

▶ **Realised investments:**  
**RM272.7** MILLION

▶ **6 FDI**  
(Foreign Direct Investment)



**RM850.1** MILLION  
of total investments

▶ **7 DDI**  
(Domestic Direct Investment)



**RM69.2** MILLION  
of approved investment

- ▶ **From the 13 newly approved (investment) projects**, 6 are classified as FDI (Foreign Direct Investment), with investments coming from countries like Taiwan, France, and Japan. The largest share of FDI came from Taiwan in the aquaculture biotechnology, with investment amounting up to RM 400 million (whole project valued at RM 2.2 billion). In addition, 7 DDI (Domestic Direct Investment) projects with investments exceeding **RM 68 million** were also approved in 2013.

### Job Creation

▶ **Creating 1,615 JOBS**  *across the AgBiotech sector*

## Strategic International & Domestic Partnerships



1

Technology Transfer Agreement between Amplio Ingredients Sdn Bhd (Amplio) and Pharma Foods International Co., Ltd. (PFI) on setting up a manufacturing plant in Malaysia for the production of "OVOPRON™", Defatted Egg Yolk Powder and Egg Oil.

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2

Joint Business Collaboration Agreement between Tropical Oyster Sdn Bhd and Bio Desaru Sdn Bhd, to develop an integrated hatchery, nursery and grow-out farm at Bio Desaru Food Valley, Johor, for the cultivation of tropical oysters for the global market.

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3

Memorandum of Understanding between Terra Garden Biotech (M) Sdn Bhd and Bio Solar Wind Energy Pte Ltd., to explore the potential of a hybrid napier grass (var. Hi-Cross) for biomass production for applications in animal feed and renewable energy projects.

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4

Memorandum of Agreement between Green World Genetics Sdn Bhd and Yuksel Seed Co., Ltd., to jointly develop and market high value hybrid seed in Malaysia and Asia Pacific.

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5

Memorandum of Understanding between Inno Integrasi Sdn Bhd and Microwell Bio Solutions Sdn Bhd, for the joint production of homogenous and pathogen-free bio-organic fertiliser (Gro Agro 6 and other proprietary blends).



## BioIndustrial

### Investment

- ▶ Approved investments:

**RM2.29** BILLION

- ▶ Realised investments:

**RM432** MILLION



**FDI**

with total approved investment:



**RM1.67** BILLION  
of total investments



**DDI**

with total approved investment:



**RM617** MILLION  
of approved investment

### Job Creation

- ▶ Creating

**390 JOBS**



across the  
*BioIndustrial sector*

### Strategic International & Domestic Partnerships



1

Memorandum of Agreement between BiotechCorp and Johor Biotechnology and Biodiversity Corporation (J-Biotech). The agreement is to facilitate further discussions between the two parties for the exchange of confidential and sensitive information necessary towards the preparation of proposals in relation to Project DAFFLESIA.

2

Memorandum of Understanding between Airestec Innovation Sdn Bhd and Automotive Development Centre (adc)-utm to establish cooperation on the activities of research, development & commercialisation programs relating to, but not limited to:-

- HVAC-automotive and building
- decontamination and treatment
- anti-corrosion and anti-microbial
- health and indoor air quality
- bio and green technology

## Strategic International & Domestic Partnerships

- 3 Collaboration Proposal between BiotechCorp and Malaysia Timber Industry Board (MTIB) in relation to the setting up of a joint developmental programme to study and assess the performance of *Leucaena leucocephala* or "Petai Belalang" (as a forest plantation) and subsequently to establish the required best agricultural practices for the species as commercial forest plantation for biomass production.

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- 4 Memorandum of Understanding between BiotechCorp, Malaysia Debt Ventures Berhad (MDV) and Malaysia Palm Oil Board (MPOB) in relation to the production of second generation fermentable sugar which will be utilised to support needs and requirements of the industrial biotechnology and life-sciences projects in Malaysia. The project will be called MY2GEN.

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- 5 Collaboration Proposal between BiotechCorp, Sabah Economic Development and Investment Authority (SEDIA) and Sabah Green Development Sdn Bhd in relation to the setting up of *Leucaena leucocephala* trial plot for research and development purposes and subsequently on the development of *Leucaena leucocephala* forest plantation in Sabah.

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- 6 Collaboration Proposal between BiotechCorp & POIC Sabah Sdn Bhd in the areas of Industrial Biotechnology Development, Healthcare Biotechnology Development, Human Capital Development and BioNexus Development in Sabah.

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- 7 Announcement of "Petai Belalang" pioneer project in Kota Marudu, Sabah, Malaysia. This initiative promoted by Sabah Green Development Sdn Bhd is in relation to the setting up of *Leucaena leucocephala* pilot project for research and development purposes and upon completion of feasibility studies, the project may be extended into the development of *Leucaena leucocephala* forest plantation in Kota Marudu, Sabah.

## BioMedical



### Investment

▶ **Approved investments:**  
**RM948** MILLION

▶ **Realised investments:**  
**RM442** MILLION

▶ **Biopharmaceutical sector contributes**



**RM477.56**  
MILLION

▶ **Medical Devices & In vitro Diagnostics (IVD) contribute**



**RM464.1**  
MILLION

From the total **Approved** Investment in 2013



**was contributed by DDI.**  
*Domestic direct investments*

- ▶ with total investments **RM 709.2 MILLION**. *The domestic investments* primarily came from the Northern region where the matured & established medical devices sector contributed **50%** of the accumulative investment.

**BiotechCorp offers facilitation** for companies from the pre-investment to post-investment stage. Regulatory Approval, Local Authority Approval, Talent Resource and Immigration Applications are among the facilitation scopes which BiotechCorp provides to the industry.

### Job Creation

▶ **Creating 2,613 JOBS**



*opportunities from the approved investments.*

## Strategic International & Domestic Partnerships

1

Build and Lease Agreement between Bio-XCell & Stelis Biopharma (formerly known as Agila Biotech Malaysia). Bio-XCell and Stelis Biopharma signed a Build and Lease Agreement (BLA) in March 2013. This agreement is towards the establishment of a customised biotech facility in the Bio-XCell Malaysia.

2

CCM Acquisition of Stake in PanGen Biotech Chemical Company of Malaysia Berhad (CCM) accelerated its foray into the biosimilars business with the purchase of equity stake in PanGen Biotech, Inc, (PanGen) a Korean biotechnology company.

In this regard, CCM's equity stake in PanGen allows its Pharmaceuticals Division to have strategic access to a biosimilar that is being produced as there are very few start-up biological companies globally with the expertise, track record and range of cell lines already developed by PanGen. This is pursuant to the collaboration facilitated by BiotechCorp between these parties to conduct clinical trials of Erythropoietin (EPO) in Malaysia to treat end stage renal failure patients.

## BIONEXUS DEVELOPMENT

### Industry Support & Evaluation



The concept store of promoting bio-based products by BioNexus Status companies was successfully set up during BioMalaysia & Bioeconomy Asia Pacific 2013 held on 21 – 23 October 2013 at Persada Johor International Convention Centre, Johor

- i. **More than 100** types of products promoted
- ii. **Promotion and awareness** of biotechnology - based products to the public

7

## Market Access

Participated & organised the participation of BioNexus status companies in local & international exhibitions, events & trade missions

- ▶ **International Exhibitions & Events**  
- Potential deal value recorded



**RM 48.75**  
MILLION

- ▶ **Organised workshop** for biotechnology industry with the support MOF, MDV, MTDC, Agrobank, SME Corp & other industry players.

8

## Facilitation on Funding

- ▶ **List of BioNexus Status companies participated in a pitching session with Bank Negara Malaysia on 25 June 2013 and 20 November 2013:**

- Inno Integrasi Sdn Bhd
- Ligno Biotech Sdn Bhd
- Biofactlife Sdn Bhd
- Bionestro Sdn Bhd
- Green World Genetics Sdn Bhd

- ▶ **As a result** of continuous facilitation in sourcing funding facilities for BioNexus status companies, a total:



**RM 59**  
MILLION

*funding facilities were approved during the year.*

9

In line with the BioNexus Bill of Guarantee No. 8, "Access to Shared Laboratories & Facilities" as well as to facilitate the translation of "Science to Business" as aspired under Phase II National Biotechnology Policy, the Shared Facilities Unit's (SFU) role is to support Malaysia's biotechnology and life sciences industry's R&D&C needs for high-end research facilities, services and expertise.

### Access to Shared Laboratories & Facilities

Access to a network of 52 BioNexus Partners (BNP) laboratories all over Malaysia from 13 IHLs, 3 RIs and 2 GLCs providing R&D&C support to bio-based companies.

- **200++ COLLABORATIONS & PROJECTS** with other bio-based companies, SME, entrepreneurs
- **42 COLLABORATIONS & PROJECTS** between BNP laboratories and units with BioNexus companies
- **4.1 OUT OF 5.0** average rating of client satisfaction with the BNP laboratories and units
- **RM 1.0** MILLION revenue generated by BNP laboratories

## Highlights for year 2013:

- ▶ **3 Outstanding BNP laboratories** were awarded during the BioNexus Appreciation Night, 21 October 2013, Thistle Hotel, Johor Bahru:
  - BNP Award for Best Agriculture Biotechnology Partner is the Herbal Product Development Laboratory of FRIM
  - BNP Award for Best Healthcare Biotechnology Partner is the Animal Toxicity Unit of Universiti Kebangsaan Malaysia (UKM)
  - BNP Award for Best Industrial Biotechnology Partner is the Fermentation Technology Unit (FTU) of Universiti Putra Malaysia (UPM)
- ▶ **3rd BNP Centre of Excellence (BNP CoE)** under Universiti Teknologi Malaysia (UTM) established as an R&D&C reference centre for Industrial BioProduct Development
- ▶ **2 BNP laboratories** obtained the ISO 17025 certification in 2013:
  - Bioequivalence Laboratory, Faculty of Medicine, Universiti Malaya
  - Human Identification/ DNA Unit, School of Health Sciences, Universiti Sains Malaysia

## INDUSTRY DEVELOPMENT

### Development of National Occupational Skills Standards (NOSS)

#### ▶ Completed the following NOSS:

- 1) NOSS Enzymatic Bioconversion level 1-3
- 2) NOSS Enzymatic Bioconversion level 4-5
- 3) NOSS Agriculture Biotechnology Laboratory level 1-3
- 4) NOSS Agriculture Biotechnology Laboratory level 4-5
- 5) NOSS Spiny Lobster Hatchery level 1-3
- 6) NOSS Spiny Lobster Hatchery Level 4-5

BiotechCorp together with Department of Skills Development (JPK) had organised the NOSS promotion event during BioMalaysia & Bioeconomy Asia Pacific Conference & Exhibition 2013 at PERSADA Johor. A total of 38 companies comprising the BioNexus Status companies, J-Biotech and its subsidiaries and BioNexus Partners Lab have attended the NOSS Promotion session.

### Advanced Bioprocess Training at Korea Research Institute of Bioscience & Biotechnology (KRIBB)

- ▶ 10 biotechnology graduates attended the 2-month training at KRIBB supervised by renowned researchers of KRIBB. One of the graduates has been accepted to work as an Assistant Researcher at KRIBB to pursue Master course at University of Science & Technology (UST), Korea.
- ▶ One of the participants from the 2010 batch, Sasikumar Rajoo has completed his Master at University of Science & Technology Korea in early 2013 and has been accepted to pursue PhD at ETH Zurich, Switzerland. ETH Zurich is ranked 12 in the World University Rankings 2013.

### Biotechnology Entrepreneurship Special Training (BeST) Programme

- ▶ **244**   **GRADUATES** *from local and overseas universities attended the BeST Programme*

Organised by BiotechCorp, BeST Programme is a special edition of graduate employability programme for biotechnology & life sciences graduates.

### BioCareer & BioEducation 2013

- ▶ **30** **Biotechnology Career** posters displayed
- 4** **Bio Cinemas** were opened for career talks & industry insight
- 14** **Learning Partners** ran the shows
- 12** **Career Coaches** shared their knowledge & experiences
- 245** **Graduates** participated



**29**

**Johor Schools** participated



**1330**

**School Students** participated



**37%**

**Highly Interested** to study Biotech



**63%**

**Will Consider** to study Biotech



**76%**

**Said biotech is** very interesting

## POLICY & REGULATORY

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### Biosafety Framework

- ▶ BiotechCorp continues to work closely with the Department of Biosafety, Ministry of Natural Resources & Environment (MONRE) in the operationalisation of the Biosafety Act and its Regulations, by facilitating biosafety submissions from BioNexus Status companies and potential investors.

BiotechCorp in collaboration with the Department of Biosafety, Ministry of Natural Resources and Environment organised a Workshop funded by the Asia Pacific Economic Cooperation (APEC) on 4 – 5 September 2013 titled “Workshop on Biotechnology Commercialisation and Trade in APEC Economies - A Biosafety Regulatory Perspective”. The proposal was submitted by BiotechCorp early 2012 and obtained approval in December 2012.

The objective of the Workshop is to facilitate knowledge and experience sharing among biosafety experts from national and international organisations and discuss best practices in biosafety compliance and encourage commercialisation of biotechnology.

### Access & Benefit Sharing (ABS)

- ▶ The Conference of the Parties to the Convention on Biological Diversity (CBD) in 2010 saw the finalisation and adoption of the “Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity”. The Nagoya Protocol is an international agreement which aims at sharing the benefits arising from the utilisation of genetic resources in a fair and equitable way. Consistent with Malaysia's commitment and obligation as a member of the CBD, under the Nagoya Protocol, a comprehensive national regulatory framework on Access and Benefit Sharing (ABS) needs to be in place.
- ▶ BiotechCorp resumes regulatory engagements with MONRE in the consultation process for the ABS laws and will continue to provide input on behalf of the industry.
- ▶ While it was earlier anticipated that the draft ABS law was to be tabled in Parliament before the end of 2013, due to the needs and requirements to seek stakeholders' inputs especially from Sarawak and Sabah, the draft ABS law will mostly likely be tabled in 2014.
- ▶ Upon its promulgation, the domestic ABS framework should provide a balanced means to ensure that Malaysia will be able to combat biopiracy.

### Intellectual Property (IP)

- ▶ In support of the government's efforts and commitment in recognising IP collateralisation, BiotechCorp continues to work closely with the Intellectual Property Corporation of Malaysia (MyIPO) and Malaysia Debt Ventures Berhad (MDV) towards the realisation of this commendable initiative which includes :

- **Training of Local IP Valuers:** The pilot IP valuation training and certification course was introduced in March 2013 to train and develop a pool of local IP Valuers. To-date, there are a total of 23 certified IP valuers in Malaysia, of which 2 are personnel from BiotechCorp.
- **The IP Valuation Model (IPVM)** was launched in November 2013 with the aim of providing the much needed clarity and standards for various stakeholders and key players in supporting the acceptance of IP rights as collateral by lenders and financiers. The launch of the IPVM marks an important milestone for moving the monetisation of IP rights to the next level.
- **Intellectual Property Financing Scheme (IPFS)** was launched in December 2013 by MDV and a collaboration agreement between BiotechCorp and MDV was signed to bring about greater access to funding for BioNexus status companies. The creation of the IPFS is expected to provide funding alternatives for companies through monetisation of their valuable IPs.

## Pharma Regulations

- ▶ The Drug Registration Guidance Document (DRGD), revised December 2013, serves as a dynamic and comprehensive guidance document for medicinal product registration.

In 2013, the following directives / guidelines were issued and/or revised :

- Drug Registration Guidance Document (DRGD) (December 2013);
  - Draft Guidance Document & Guidelines for Vaccine Lot Release Malaysia (November 2013);
  - Guidelines on Good Distribution Practice (GDP) 2nd Edition (2013); and
  - Malaysian Variation Guideline for Pharmaceutical Products 1st Edition (2013).
- ▶ Throughout 2013, Malaysia continued to play an active role in harmonisation efforts through the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG), the Traditional Medicines and Health Supplement Product Working Group (TMHS PWG) as well as the Medical Devices Product Working Group (MDPWG).
  - ▶ Through the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) participation, BiotechCorp was able to keep track on the work programme progress and the time frame targeted in harmonising standards and reducing technical barriers towards a single market by 2015.

## International Accreditation (GLP)

- ▶ Effective from 10th April 2013, Malaysia is officially a non-member with full adherence to the Organisation for Economic Cooperation and Development (OECD) Council Acts related to Mutual Acceptance of Data (MAD) in the Assessment of Chemicals on Good Laboratory Practice (GLP).
- ▶ The GLP Compliance Programme will help our test facilities gain acceptance of their non-clinical health safety studies into OECD countries and other members who adhere to OECD.

## TECHNOLOGY MANAGEMENT OFFICE

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**Biotechnology Technology Management Sdn Bhd (BTM)** incorporated on 16 March 2011, is a wholly owned subsidiary of the Malaysian Biotechnology Corporation Sdn Bhd (BiotechCorp). BTM in the interim, functions as a division of BiotechCorp also known as the Technology Management Office (TMO). The key responsibilities of TMO are to manage, develop and commercialise the platform technologies acquired by BiotechCorp under the Biotechnology Acquisition Programme (BAP) during the 9th Malaysian Plan.

Following are the technologies being managed by TMO:

### Supercritical Fluid Extraction Platform Technology

- ▶ The Supercritical Fluid Extraction Centre (SFC) located at Universiti Putra Malaysia (UPM) has been successfully operationalised after having fulfilled the mandatory safety requirement set by the Department of Safety & Health (Dosh). TMO has also successfully facilitated the training for the operators of the hardware at SFC.

### Marker Assisted Selection Platform Technology

- ▶ The Centre for Marker Discovery and Validation (CMDV) has been fully set up and commenced its operations in 2011. The centre offers services to the industry with transactions valued at approximately RM 170,000 in 2013 and set to generate further increase in transaction value in the coming years.

### DotScan Platform Technology

- ▶ This platform technology with its two technology custodians, namely the Institute for Medical Research (IMR) and UPM are conducting research towards the development new applications utilising the DotScan Platform Technology. In addition, this platform technology has successfully obtained additional research funding from the Ministry of Science, Technology and Innovation (MOSTI) e-Science fund.

### Nanotechnology Platform

- ▶ The Nanotechnology Platform under the NanoBiotechnology Research and Innovation Cluster (NanoBRI) under the Institute for Research in Molecular Medicine (INFROMM), Universiti Sains Malaysia (USM). Research by NanoBRI includes the design and development of nanoparticles, nanocolloids, reagents, drug and molecule carriers, cellular imaging and diagnostic platforms in addition to developing a method of production of gold and iron oxide nanoparticles and its conjugation with biomolecules.

# MOVING FORWARD

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## BIOECONOMY DEVELOPMENT

### i) Evaluation & Implementation

- ▶ The Evaluation & Implementation (E&I) team will continue to identify potential high impact bio-based project to be part of the Bioeconomy Transformation Programme (BTP) through direct engagements with key stakeholders across the nation from both the public and private sectors. The team will continue working toward the targets set for the BTP (including the impact of the Bioeconomy Malaysia Accelerator Programmes):-
  - GNI contribution of RM 48 billion in the year 2020;
  - 170,000 job opportunities; and
  - RM 50 billion in investment by 2020
  
- ▶ In order to achieve the targeted KPI, the team will targeted KPI, the team will:
  - Continue organising and participating in flagship Bioeconomy events and roadshows locally and internationally to enhance Malaysia's presence and standing in Bioeconomy.
  - Identify and increase the number of Trigger Projects included in the Bioeconomy Transformation Programme through close collaboration with internal and external stakeholders.
  - Undertake continuous communication, awareness and promotion campaigns on the Bioeconomy Transformation Programme, targeting the private sector, ministries, financial institutions, researchers and academicians, media as well as the general public.
  - Increase collaboration and partnership with regional and international networks to enhance the Bioeconomy ecosystem.

### ii) Knowledge Management

- ▶ Knowledge Management will look into key issues specifically to retain crucial information and data within the organisation:
  - Develop value-added services for the stakeholders by repackaging information and data for productive use.
  - Implementation of knowledge management environment and programs aligned with Resource Centre's services and importance.

Knowledge Management needs to reposition and enhance itself to act as a knowledge centre for small and medium businesses, providing knowledge demanded by the entrepreneurs and business skills with competitive intelligence services.

## BUSINESS DEVELOPMENT & INVESTMENT

### i) AgBiotech

- ▶ Moving forward, the Business Development & Investment (AgBiotech) division hopes to enhance its efforts towards creating a more conducive ecosystem in order to enable the AgBiotech industry to grow, expand, and the companies to become global players. Emphasis will be made towards ensuring the food and feed security for the nation are met, which includes producing more and safe food in a sustainable manner. We strongly believe that the development of a more conducive ecosystem would be able to attract investments in agriculture biotechnology, thus, creating more high impact projects, job opportunities and value for the nation as a whole. The following are the focus areas for AgBiotech :-



#### AQUACULTURE

Promoting high value aquaculture projects that emphasise on efficiency & sustainability

- Fish
- Crustaceans
- Sea Cucumber
- Seaweed
- Algae
- Feed additives



#### CROP

Promoting biotech based agriculture practices to maximise productivity & sustainability

- Soil & Plant Enhancers
- Bio-fertilisers
- Bio-control
- Elite planting material
- Bio-pesticides



#### NATURAL PRODUCT

Promoting commercialisation and sustainable use of natural resources

- Nutraceuticals
- Flavours & Fragrances
- Stabilisers & Emulsifiers
- Cosmeceutical
- Botanical extracts
- Functional Food



#### LIVESTOCK

Promoting biotech based husbandry practices to maximise productivity & sustainability

- Animal Nutrition
- Downstream products
- Veterinary Health Products

## ii) BioIndustrial

- ▶ BiotechCorp will employ new strategies in building the industrial biotechnology sector. BiotechCorp will continue to anticipate new emerging sectors within Industrial Biotechnology, to seek and secure high impact nucleus investments; high impact investments are those that are high in quantum and will lead to a spillover and multiplier effect towards the broader economy.

The main feedstock that will be focused on are oil palm biomass, palm oil and its derivatives, such as glycerin and carotenoids. Additionally, feedstock from other crops is also being considered, such as *Leucaena leucocephala* and rice husk/straw as well as lignin from these crops. Gaseous feedstocks, such as methane will also be included.

The industrial biotechnology has to be inter-related with the existing industries in order for the industry to advance and sustain. For example, the Kertih Biopolymer Park (KBP) is leveraging on the existing oil and gas industry in the East Coast Economic Region (ECER).

The main strategy to move the industrial biotechnology forward in Malaysia is through the creation of bio-clustering. This includes the partnership of BiotechCorp with strategic economic corridors, such as ECERDC, NCIA, SEDIA, POIC, and SCORE. In addition, strategic partnership with international institutions will enhance BiotechCorp's capability to expand its network overseas.

In order to attract more investments in the industrial biotechnology industry in Malaysia, BiotechCorp will need to create conducive and attractive environment to increase Malaysia's competitive advantages over neighboring countries.

BiotechCorp will assist with the expansion of cluster supporting businesses by identifying relevant companies that have appropriate technology platforms required by incoming investments. The development of the clusters is seen as a strategic move for Malaysia, as it will lead to spillover of investments (i.e. power generation plants, feedstock plantations, waste management, etc.), which will support the companies in the said clusters. This will also maximise the value of the feedstock available in the region, thus leading to increase in the productivity of the companies in the cluster (located near the feedstock source). This strategy will also create momentum for BiotechCorp in which success stories such as the Kertih Biopolymer Park will attract further investments into Malaysia.

### iii) BioMedical

- ▶ Biomedical industry is expected to contribute to the nation's development by leveraging on the existing biomedical ecosystem, value chain and cross-ministries cooperation. The ultimate goal is to provide better and affordable healthcare solutions to improve rakyat's quality of life and the creation employment opportunities, increase the Gross National Income (GNI) contribution from biotechnology sector and increase in product export.

BiotechCorp outlines focus areas that are in line with the National Biotechnology Policy (NBP) and Bioeconomy Transformation Program (BTP) as well as Economic Transformation Program (ETP). The sectors are namely Biopharmaceutical, Medical Devices and In-Vitro Diagnostic and Emerging Biosciences. The three sectors are subcategorised into specific subsectors as below:



#### Biopharmaceuticals

Small molecules and large molecules



#### Medical Devices & Diagnostics

Orthopaedic, Cardiovascular (CVS), Molecular Diagnostics, Surgical and Other Medical Devices & Diagnostics



#### Emerging Life Sciences

Cellular & Gene Therapy Products, Bio Services (Contract Manufacturing & Contract Research), Pharma Nutrition and Other Biosciences

#### ▶ Building the ecosystem based on value chain approach and targeted focus areas:

- 1 Increasing Clinical Research and Capabilities:** Clinical research is one of BioMedical's focus areas under Emerging Bioscience sector. BiotechCorp along with Clinical Research Malaysia (CRM) will continue to attract more clinical research to be conducted in Malaysia.
- 2 Developing a Sustainable Biomedical Ecosystem:** BiotechCorp is strengthening Malaysian biomedical ecosystem which is clustered into four major components; Basic Research, Developmental Research, Manufacturing and Commercialisation & Care Delivery.
- 3 Enhancing Market Access:** In order to position Malaysia as a preferred investment destination, access for the product/ service providers to the local, regional and global market is an important feature that they will take into consideration. BDI BioMedical has been significantly involved in industry dialogues and technical committee to provide regulatory, policy, trade and market access.
- 4 Increasing Visibility of Malaysia as a Biomedical Hub:** BiotechCorp will leverage on Malaysia's advantages that are recognised globally: ease of doing business, cost-competitiveness, multi-lingual and trainable talents, well-established regulatory regime and pro-business government. BiotechCorp will participate in flagship events such as JP Morgan Healthcare Conference and BIO San Diego 2014 via sponsorship and speaking slots.

## BIONEXUS DEVELOPMENT

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▶ Several key initiatives for BioNexus development are as follows:

- Intensify facilitation and engagement with BioNexus companies.
- Increase focus on market access penetration by BioNexus companies in Malaysia and also the global market.
- Create a retail market platform for locally produced biotechnology related products aiming at intensifying visibility and market acceptance.
- Collaborate with other agencies in growing / developing BioNexus companies (i.e. CradleFund, Malaysian Technology Development Corporation, Unit Peneraju Bumiputera, SME Corporation).
- Collaborate with Bank Negara, government funding agencies, local Developmental Financial institution (DFI) & Financial Institutions to assist BioNexus companies in sourcing funds to commercialise their products/services or expand their business.

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## INDUSTRY TALENT DEVELOPMENT

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- ▶ BiotechCorp will intensify its effort to ensure the biotechnology workforce will be strengthened through the development of human capital and supplying the right talent to the industry. A complete roadmap will be drawn on developing talent to ensure quality talent to be channelled to the industry.

▶ Strategic Initiatives

- 1 Intensify communication and awareness on biotechnology education and careers via career talks and career carnivals.
- 2 Bridge the industry updates into the universities through incorporating industry driven module in the universities' curriculum.
- 3 Extend the BeST Programme to more graduates in collaboration with Industry Centre of Excellence (ICOE) Biotechnology of Ministry of Education.
- 4 Prepare the workforce with competencies required to support global business phase by developing Executive MBA Biotechnology, co-developed by BiotechCorp & Universiti Malaysia Pahang (UMP).

## POLICY & REGULATORY

- ▶ As the Malaysian biotechnology industry moves to the final leg of the 2nd Phase of the NBP, future work in areas of focus include:

### 1 Biosafety and ABS

BiotechCorp to continue engagements with the Biosafety Department, in its efforts to advocate the development of a set of balanced and industry-centric regulations to ensure compliance and facilitate the growth of the biotechnology sector.

### 2 Intellectual Property

BiotechCorp to continue working closely with MyIPO and MDV to encourage and guide BioNexus status companies to avail themselves to the Intellectual Property Financing Scheme (IPFS).

### 3 Pharma Regulations

BiotechCorp will continue to participate and contribute to the development of pharmaceutical regulations including harmonisation of regulatory framework for ASEAN region. With our strong relationship with the regulatory stakeholders, we will provide continuous and constructive inputs from the industry perspective to drive the healthcare biotechnology development.

### 4 International Accreditation

BiotechCorp shall continuously support all initiatives in encouraging test facilities from BioNexus status companies to be OECD certified for easy access to the international market without going through duplicative testing thus saving cost, time and resources as well as reducing trade barriers.

## TECHNOLOGY MANAGEMENT OFFICE

- ▶ Technology Management Office will continue to manage and commercialise the four platform technologies in addition to expanding its role to serve the industry via the following strategies:
- Offering IP commercialisation and transaction services to universities, research institutes, BioNexus Partner laboratories and BioNexus companies.
  - Intensifying engagement with targeted industry players and commercial partners to enhance awareness and accelerate the adoption of the technologies as well as expanding the client base for the same.
  - Boosting utilisation of the platform technologies via comprehensive research and development projects, collaborations with industry as well as funding assistance for national interest projects.

# NOTES



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