



# Singapore CA Qualification Examination

# **INTEGRATIVE BUSINESS SOLUTIONS**

# ADVANCE INFORMATION

# Monday, 17 May 2021

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### WARNING

Candidates **must not under any circumstances** contact any similar company or its agents to obtain research data, and they must use **ONLY PUBLICLY AVAILABLE INFORMATION.** Under no circumstances should they seek to use unpublished or private information.





Dear Candidate,

This information package contains the **Advance Information** for the Integrative Business Solutions (IB) module final examination to be held on **Monday, 7 June 2021**. A checklist of the documents (Exhibits) contained in this information package is provided on the following page. It is your responsibility to ensure that you have received every document listed.

Your task now is to familiarise yourself with this information including analysing the data provided. In addition, you are encouraged to undertake further research to form a holistic picture of the industry and markets in which the case study company is operating, and the general economic and business environment. Diligent preparation is essential for success in the IB Examination. Guidance on preparing for the IB Examination is covered in your IB Toolkit.

**The IB examination will be conducted using Cirrus.** Please download this Advance Information to the hard drive on your laptop prior to the examination day. Although you will have full access to the hard drive on your laptop during the examination, you are strongly advised to bring your notes and other preparatory workings in **hard copy format,** as well as a standalone calculator that complies with the SAC's regulations for your examination.

You will also receive additional information (Examination Day Documents) on the case study company on the day of the IB Examination. The Examination Requirements will be included within Cirrus. Follow the instructions in Cirrus to download the Examination Day Documents. You are not allowed to print the Examination Day Documents on the day of examination. The Examination Day Documents complete the case study scenario and set out the requirements for the report that you are required to write. The IB Examination will be an open-book examination of 4 hours 30 minutes duration. Your formal report will cover four specified areas, one of which will be to write an Executive Summary. Please note that only your report commentary (including the assumptions made), appendices, and workings entered in Cirrus on the day of the examination will be marked.

#### **Biomore Pte Ltd**

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Note: Unless otherwise stated, all dollar amounts (\$) are in Singapore dollars.

#### **EXHIBIT 1**

#### Biomore Pte Ltd origins and company background

#### History

Biomore is a biopharmaceutical company based in Singapore. Its parent company, OneWorld BioPharm (OWB) is headquartered in the United States.

OWB is a global biopharmaceutical company and is divisionalised by region. Biomore, is a separate legal entity that develops, manufactures and sells its own products globally.

Unlike wholly synthesised pharmaceuticals, biopharmaceuticals (also known as biologics) are manufactured using living biological systems such as animal cells and micro-organisms. They form the basis for numerous revolutionary treatments for patients suffering from chronic and life-threatening conditions like cancer; cardiovascular, metabolic and neurological diseases; and genetic disorders.

Biomore opened in Singapore in the early 1990s. Over the years, it has invested over \$2 billion into its various facilities in Biopolis – the research and development centre for biomedical sciences in Singapore. In 2009, it acquired Pasir Bio, a large pharmaceutical company in Singapore and took over its manufacturing and R&D facilities, enabling Biomore to significantly expand operations. More importantly, this acquisition enabled Biomore to integrate the acquired company's cutting-edge proprietary research into its own operations.

Five years later, in 2014, Biomore expanded into the IT field, investing \$8 million in opening an IT Centre. Not only did this facility provide innovative IT services in collaboration with start-ups and local hospitals, it worked closely with an international network of Biomore IT Centres to advance digital solutions for biopharmaceutical R&D and manufacturing.

In 2020, the company began a three-year planned investment project of \$3 billion in upgrading the machinery at the various factories.

Biomore employs over 1,000 people in Singapore and produces products that range from active pharmaceutical ingredients to finished drugs for diabetes, cancer, hepatitis © 2021 Singapore Accountancy Commission Page Al-4 of 44 C and more. It contributes significantly to its parent company's global business, managing key products that support more than 30% of the group's total global revenue.

#### **Recent Activities**

Biomore was responsible for 40 new product and device registrations in the Asia-Pacific Region (APAC) in 2019, which was more than any other region within its parent company's global business. For the past eight years, its APAC operations remained the third highest earner for its parent company, following behind the United States and Europe/Middle East/Africa, with \$7.995 billion in revenue in 2019.

Biomore's strongest sales are in human health pharmaceuticals and vaccines, with key growth drivers in cancer treatment and animal health products. Its top performing product is a cancer drug that brought in \$1.6 billion in global sales in 2019, which represented a growth of 58% year-on-year. In the coming years, Biomore will continue to invest heavily in oncology, which is projected to remain a key industry driver, with a forecasted compound annual growth rate (CAGR) in revenue of 12% from 2021 to 2024.

#### Competition

Biomore's competitors include Merck & Co Inc (trading as MSD outside the United States), GlaxoSmithKline Plc and Amgen.

#### Merck & Co Inc

Merck is based in the United States, and trades as MSD outside of the United States. It established its first Singapore manufacturing plant in the 1990s and later merged with Schering Plough. MSD Singapore now forms the headquarter of the company's Asia-Pacific operations. It produces active pharmaceutical ingredients and finished products. In 2019, it also began producing biologics. In addition to manufacturing, MSD also operates a Translational Medicine Research Centre, which focuses on cutting-edge research, as well as a Global IT Innovation Hub, which leverages digital transformation, cybersecurity and bioinformatics to drive healthcare solutions. Its investments into its Singapore operations totalled over US\$2 billion.

#### GlaxoSmithKline Plc

GlaxoSmithKline is based in the United Kingdom. It operates three manufacturing plants in Singapore. The first plant was established in 2006 and was subsequently upgraded in 2012 and again in 2015 at a total investment of over \$169 million. This site produces an ingredient used to manufacture antibiotics. The second plant was established in 2009 at a cost of \$510 million and is used to manufacture vaccines. The third plant, which is equipped with award-winning sustainable processes and green technologies, manufactures active pharmaceutical ingredients. GlaxoSmithKline established its Asia-Pacific headquarter in Singapore in 2017.

#### Amgen

Amgen is based in the United States. It established its first Asian manufacturing facility in Singapore in 2014. This next-generation Biomanufacturing Facility, which features a modular design incorporating cutting-edge technologies, represents an investment of over US\$150 million. Although it is 16% the size of a conventional manufacturing plant, it is expected to generate the same annual output while consuming less energy and water and producing less waste and emissions. Its second manufacturing plant formally underwent testing in 2017 and now produces active pharmaceutical ingredients.

#### Summary consolidated management accounts 2018 – 2020

#### **Biomore Pte Ltd**

#### Statement of Profit or Loss for the year ended

	Notes	31 March 2020 \$million	31 March 2019 \$million	31 March 2018 \$million
Revenue	1	10,394	7,995	6,150
Cost of sales:		·		·
Materials		(1,554)	(1,199)	(923)
Production wage costs		(935)	(622)	(444)
Depreciation of land and				
buildings and factory equipment -		(722)	(400)	(506)
production Total cost of sales		(732)	(499)	(506)
		<u>(3,221)</u> 7,173	<u>(2,320)</u> 5,675	<u>(1,873)</u> 4,277
Gross profit		7,175	5,075	4,277
Selling and admin expenses				
Salary costs - sales and admin		(1,039)	(890)	(677)
Bonus costs - sales		(520)	(340)	(260)
Depreciation of office equipment		(0=0)	(0.0)	()
and furniture		(21)	(21)	(20)
Other selling and admin costs		(433)	(327)	(144)
Total selling and admin		(0.040)		(4,404)
expenses		(2,013)	(1,578)	(1,101)
Pasaarah and davalanmant aasta				
Research and development costs Salary costs research		(832)	(600)	(482)
Depreciation of research		(002)	(000)	(402)
equipment		(16)	(15)	(15)
Other research costs		(246)	(231)	(144)
Amortisation of development				
expenditure	3	(1,362)	(1,014)	(867)
Total research and development costs		(2,456)	(1,860)	(1,508)
Operating profit		2,704	2,237	1,668
Finance charges	5	(163)	(122)	(112)
Profit before tax	5	2,541	2,115	1,556
Taxation		(432)	(360)	(284)
Profit after tax		2,109	1,755	1,272
		2,100	1,700	1,272
Dividends paid		(551)	(525)	(500)
Retained profits		1,558	1,230	772
		,	- ,	

#### Statement of Financial Position as at

	Notes	31 March 2020 \$million	31 March 2019 \$million	31 March 2018 \$million
Non-current assets				
Property, plant & equipment	2	3,100	2,412	2,451
Intangible assets	3	6,876	4,753	4,267
Goodwill	4	1,700	1,700	1,700
Total non-current assets		11,676	8,865	8,418
Current assets				
Cash and cash equivalents		1,105	1,107	109
Trade receivables		1,974	1,520	1,170
Inventories		803	578	429
Total current assets		3,882	3,205	1,708
Total assets		15,558	12,070	10,126
<i>Equity</i> Share capital Retained profits <b>Total equity</b>		1,000 6,311 7,311	1,000 4,753 5,753	1,000 3,523 4,523
Non-current liabilities				
Long term loan from parent company	5	3,800	3,800	3,800
Long term borrowings from banks	5	2,100	760	475
Total non-current liabilities		5,900	4,560	4,275
<i>Current liabilities</i> Accounts payable Current portion of long-term debt Tax	5	1,765 150 <u>432</u>	1,272 125 360	944 100 284
Total current liabilities		2,347	1,757	1,328
Total equity and liabilities		15,558	12,070	10,126

#### Notes to the management accounts:

#### 1. Analysis of revenue by therapeutic area for the year ended:

	31 March 2020 \$million	31 March 2019 \$million	31 March 2018 \$million
Pharma respiratory	961	769	615
Pharma oncology	3,375	2,411	1,722
Pharma diabetes	3,082	2,558	1,968
Vaccines	2,395	1,842	1,538
Animal health	581	415	307
Total	10,394	7,995	6,150

#### 2. Property, plant and equipment

Carrying value	31 March 2020 \$million	31 March 2019 \$million	31 March 2018 \$million
Land and buildings	806	828	850
Factory equipment - production	2,152	1,444	1,466
Laboratory equipment - research	80	77	75
Office equipment and furniture	62	63	60
Total	3,100	2,412	2,451

Depreciation charge	Year ended 31 March 2020 \$million	Year ended 31 March 2019 \$million	Year ended 31 March 2018 \$million
Land and buildings	(22)	(22)	(22)
Factory equipment - production	(710)	(477)	(484)
Research equipment	(16)	(15)	(15)
Office equipment and furniture	(21)	(21)	(20)
Total depreciation	(769)	(535)	(541)

The following rates of depreciation are used for property, plant and equipment: Land and buildings - 2% of cost Factory equipment - 30% reducing balance Laboratory equipment - 20% reducing balance Office equipment and furniture - 33% reducing balance

#### 3. Intangible assets - capitalised development expenditure

		31 March 2019	
	\$million	\$million	\$million
Cost	13,657	10,172	8,672
Accumulated amortisation	(6,781)	(5,419)	(4,405)
Carrying value	6,876	4,753	4,267
Amortisation during the year	(1,362)	(1,014)	(867)

Development expenditure on specific products is capitalised. Amortisation of the expenditure on each product begins during the year when the product is first manufactured for sale. Each product is amortised over its expected commercial life, which is generally 10 years.

The carrying values of the five largest products were as follows:

	31 March 2020
	\$million
Pembrolumab (Cancer)	900
Abroxanib (Cancer)	450
Tiotryollate (Respiratory diseases)	400
Acidintutopium (Respiratory diseases)	800
Biopeptiline (Diabetes)	1,120

#### 4. Goodwill

Goodwill relates to the acquisition of Pasir Bio in 2009. Goodwill is not amortised but the company considers whether the goodwill has become impaired on an annual basis.

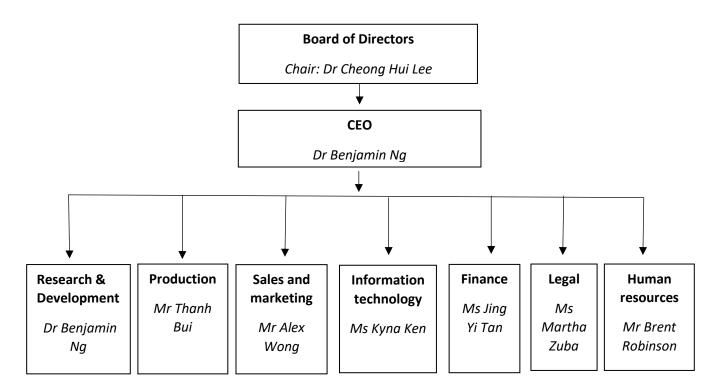
#### 5. Non-current liabilities

The long-term loan from the parent company is repayable in full in the year 2030. Interest on the loan is 2.5% per annum.

Long term borrowings from banks relates to finance raised from banks in Singapore. The loans are repayable in annual instalments over a period of ten years. The rate of interest on such loans is currently 3%.

#### **Organisational Structure of Biomore Pte Ltd**

Biomore has a well-defined organisational and reporting structure as laid out in the following organisational chart:



The following are members of the Board of Directors:

Director	Background and responsibilities
Dr Cheong Hui Lee	Chair of the Board of Directors
	Dr Cheong was appointed non-executive Chair of Biomore in December 2018. He enjoys a successful business career, holding directorships in a number of companies in Singapore. Prior to this, he worked for First International Bank for thirty years as a corporate finance executive.
Dr Benjamin Ng	Chief Executive Officer (CEO)
	Dr Ng joined Biomore as CEO in 2015. Prior to this he was head of Research and Development (R&D) at Andromeda Pharma in Singapore, where he spent the first twenty years of his career. He graduated from the National University of Singapore where he studied Human Biology. Dr Ng also heads up the R&D department at Biomore.

Mr Thanh Bui	Production Director
	Mr Bui became an employee of Biomore in 2009 when Biomore took over Pasir Bio. At the time, he was the Production Director for Pasir Bio. After the integration of Pasir Bio into Biomore, Mr Bui became a Vice President of production, and was promoted to the role of Production Director of Biomore in 2014. Mr Bui holds a bachelor's degree in Industrial Engineering from the Ho Chi Minh City University of Technology.
Mr Alex Wong	Sales and Marketing Director
	Mr Wong was recruited as Sales and Marketing Director in 2019. Prior to this he worked in the marketing department of a major multinational chemicals company, based at their Asian regional headquarters in Malaysia. Alex graduated from the University of Malaya with a bachelor's degree in marketing. He also holds an MBA from INSEAD.
Ms Kyna Ken	IT Director
	Ms Ken joined Biomore in 2017 as head of IT security. She was promoted to the role of IT Director in 2019. Before joining Biomore, Kyna had worked for e-commerce giant Alibaba in a number of technical roles. She holds a master's degree in Information Technology from the James Cook University of Singapore.
Ms Jing Yi Tan	Finance Director
	Ms Tan joined Biomore in 2010 as a management accountant. Since then she has held several positions within the finance department at Biomore and was appointed Finance Director in 2018. She is a qualified Chartered Accountant. She holds a bachelor's degree in Economics from the National University of Singapore.
Ms Martha Zuba	Legal director
	Ms Zuba joined Biomore in 2012 as in-house legal counsel. She became a member of the Board of Directors in 2014. Prior to joining Biomore, Martha worked as a Director for a multi-national law firm based in Singapore office. She is a member of the Singapore Bar.

Mr Brent Robinson	Director of Human Resources
	Mr Robertson joined Biomore in 2016 as Director of Human Resource. Prior to joining Biomore, Brent worked as a Human Resource Manager in a large bank in Singapore. Brent is a British citizen who moved to Singapore in 2014. He is a member of the British Chartered Institute of Personnel and Development, and graduated from the University of Newcastle upon Tyne.
Mr John Roberts	Non-executive Director
	Mr Roberts is the Director of overseas operations for OneWorld BioPharm (OWB), the parent company of Biomore. He represents OWB at Biomore Board meetings. He has worked for OWB as Overseas Operations Director since 2015. Prior to this, he worked as international sales manager for Cupertino Gene Therapies. Mr Roberts graduated from the University of Pennsylvania with a master's degree in biotechnology.

The full Board of Directors meets quarterly, to approve budgets for research and development (R&D), to discuss performance and strategy, and to approve the financial statements and other statutory matters requiring Board approval.

The Management Board is a committee made up of the Executive Directors. It meets weekly to discuss current operational developments. It can also approve research expenditure in emergency situations, provided that the Non-Executive Directors are contacted and asked to give approval by email.

#### Research and development (R&D)

The R&D department is considered to be the most important part of Biomore as it is where the products that will become the future of the company are developed. All R&D activities are located at the company's head office in Biopolis. The department has also developed networks with several universities and other research institutions, and these account for approximately half of Biomore's pipeline.

The department is split into three sub teams:

**Discovery** – researches new potential remedies, and tests promising new remedies on animals. The department is given an annual budget, and it is expected to identify at least twenty new potential products per year.

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**Clinical trials** – organises clinical trials for the products that have successfully passed the animal testing which takes place in the discovery department. The team includes Biomore's global study teams, clinical staff (who administer the drugs to the volunteers during trials) and administrative staff (who organise the trials). Trials take place in many geographical locations, so staff are required to travel and stay at the location for the duration of the trial. A budget for clinical trials of each individual drug must be approved by the Board of Directors, as trials are an extremely costly process, costing as much as US\$40 million for one drug. Some trials are outsourced to partners, including other OWB owned companies, in which case the clinical trials team oversees the partners' work.

**Regulatory approval** – this department deals with the drug regulatory authorities in many countries throughout the world. In some countries, such as the United States (US), the parent company's own regulatory staff will apply for the approval, but Biomore's regulatory staff must liaise with the parent company staff and pass on any information required to assist in the approval process. Biomore's regulatory department also helps other companies from within the OWB group to obtain licenses to sell their products in South East Asia. A system of transfer prices is used between the group companies for such cooperation.

Biomore's policy is that no regulatory approval process for any product in any territory may begin until approval has been given by the Board of Directors.

#### **Production**

The production department manages the manufacture and packaging of drugs. In addition to the factory in Biopolis, Biomore owns factories in India, Vietnam, Hungary, Russia, New Zealand and the US. The managers of these factories report directly to the Production Director.

Biomore also uses contract manufacturers, particularly in locations where it is not feasible to supply from Biomore's own factories. These contract manufacturers include other OWB subsidiaries and external companies.

Included within the production department is the production planning team. They work closely with the sales department on planning production quantities, and based on © 2021 Singapore Accountancy Commission

these, decide which manufacturing facilities will be used for particular customers before placing orders with them.

Each factory has its own purchasing department which sources intermediate and raw ingredients for production. Some of these are ordered through Biomore's central purchasing department in Biomore, but some products are ordered locally where there is a local supplier.

#### Sales and marketing

The sales and marketing department is based in Biopolis, but the company has satellite offices around the world, dealing with sales and marketing in particular countries. All sales staff are given a fixed salary and a generous bonus scheme, based on annual sales. The sales and marketing budget is approved by the Board of Directors annually, but the Head of sales and marketing has autonomy in how the budget is allocated between the different offices.

#### Information Technology

The IT department plays two roles. Firstly, it supports the IT and other technological needs of Biomore. Secondly it provides services externally to customers, through the IT centres.

Biomore's IT department is becoming an extremely important part of the company. The use of techniques such as deep learning and artificial intelligence help the research scientists identify relationships much more quickly. This can be used, for example, in the discovery department when trying to identify remedies for particular ailments.

#### Finance

The finance team is split into the following sub teams:

Accounts - produces the statutory financial statements of Biomore as well as monthly management accounts. The department uses cost accounting to ensure that costs to date on all products in development are tracked, and these are provided in all the

management accounts to enable the management team to make decisions on whether to continue with the particular drugs.

**Treasury** - deals with short term liquidity needs or surpluses. It also hedges foreign currency risks. This department liaises closely with the parent company treasury department.

**Finance** - deals with raising funds for investments. Some funds come in the form of loans from the parent company, but debt finance is also raised locally.

#### Legal

The legal department deals with intellectual property issues, such as registration of patents. When a patent is registered in a particular jurisdiction, Biomore has the exclusive right to sell it there. This stops other companies from potentially copying intellectual property developed by Biomore. Currently there are no single international patents, so patents must be registered in each jurisdiction where Biomore wishes to protect its intellectual property. Patents have a limited life - typically 10 years. After this period, other companies may sell copies of the drug, referred to as generic drugs.

The legal department also negotiates contracts with the many partners that Biomore does business with.

#### Human resource

Human resource is involved in the recruitment and retention of talented individuals. The department supports the recruitment process, and the development and appraisal system within Biomore. It ensures that the company complies with relevant laws relating to employment in all the countries where Biomore employs staff.

#### **Biomore Pte Ltd's Operations**

#### Key areas of operation and revenue

Biomore is in the business of discovering, developing, manufacturing and marketing biologics in order to directly improve the health of people and animals around the world. It focuses primarily on the world's most urgent health challenges, including cancer, diabetes, vaccines, cardiovascular diseases, infectious diseases, respiratory diseases and acute hospital care. It also has a strong business in animal health products.

One of Biomore's core areas of business involves the discovery, development and clinical trials of novel biologics such as gene and cell therapies, therapeutic proteins, monoclonal antibodies and vaccines. It also develops biosimilars, which provide patients with a safe and effective treatment alternative for about 27% less than the original, since they generally involve lower R&D costs for Biomore.

Biomore also manufactures, packages and distributes its products to more than 140 markets worldwide. Its interdependent global manufacturing network includes its local facilities, along with external contractors, suppliers and partners that enable it to broaden its market access. The company's key customers include hospitals, clinics, insurers, pharmacies, retail outlets and patients.

Global sales and marketing is another core area of business for Biomore – and one of its most significant costs. Sales and marketing revolves around identifying, anticipating and providing solutions for customers around the world. Like other pharmaceutical companies, Biomore's sales and marketing efforts primarily target practicing healthcare professionals, although direct-to-customer marketing is growing. Pharmaceutical sales is a competitive field, and Biomore invests heavily in attracting high-quality talent through attractive compensation, state-of-the-art data analytics, networks and partnerships.

A new and emerging area of business for Biomore involves digital strategy. It recently opened an IT Centre that works closely in collaboration with an international network

of Biomore IT Centres to provide innovative IT services to the public, as well as to advance digital solutions for biopharmaceutical R&D, manufacturing and sales.

#### **Drug development**

Because patent protection for drugs is limited, pharmaceutical companies can expect to see a sharp drop in sales as soon as their patent for a group of products expires and they no longer enjoy market exclusivity. A new drug takes an average of 14 years and \$1.7 billion to develop, which is why Biomore invests heavily in maintaining a constant production pipeline in order to continue developing products that will fund future development and enable the company to remain competitive in the market.

Across the globe, Biomore currently has 47 products in the development pipeline or under regulatory review. It prioritises advanced projects that address the world's most critical medical needs while delivering value for patients, physicians and other stakeholders like insurers. These priorities align with the current and projected global burden of disease as defined by the World Health Organisation. Other factors that determine priority include commercial viability and scientific value.

#### **Drug discovery**

Drug development begins with discovery, which lasts for an average of four to five years. The goal is to identify and validate novel therapeutic targets and drug candidates that can be scaled up and advanced to pre-clinical development and toxicology studies. Thousands of compounds are developed and screened in Biomore's labs in order to identify just a small number of promising candidates, making drug development a time-consuming and costly process.

Promising candidates progress to pre-clinical development, where they are optimised and exhaustively tested for safety and effectiveness before human trials can begin. These begin with stringent laboratory tests, followed by animal testing, which is conducted in compliance with local and international regulatory requirements and in an ethical manner. This process typically continues for approximately one year. Once drug candidates are ready for human trials, Biomore scales up production to ensure a sufficient supply for global clinical trials.

#### **Clinical trials**

Only a very limited number of drug candidates emerge through animal testing to human clinical trials, which can take more than five years on average. Typically carried out in three to four phases, clinical trials systematically test investigational drugs and vaccines on human volunteers in order to determine their safety, efficacy and dosage, with the aim of producing evidence that the benefits of the investigational drug outweigh the risks.

Each clinical trial programme is developed and monitored by Biomore's global study teams as well as local clinical investigators and external expert consultants. This is done in accordance with Biomore's research policies, comprehensive regulatory requirements and guidelines, as well as global standards. To ensure that studies determine drug safety and efficacy across diverse patient populations, Biomore's clinical trials take place across more than 50 countries in all regions of the world. About 22% of the company's trial patients are based in APAC, and more than 50% are based in the United States.

#### **Regulatory approval**

Once trials are completed, documentation and data are submitted to local and international regulators requesting approval to market the new drug for human use in their respective jurisdiction, e.g. the Health Sciences Authority for approval in Singapore and the US Food and Drug Administration in the United States. From there, it typically takes another two years before a drug can be launched. Even after drugs are approved, Biomore works with regulators and healthcare professionals to actively monitor its products. This enables the company to monitor the safety profile of its products and provide important information on long-term benefits and side effects. Adverse experiences of patients are also monitored by a global team that is trained to identify, review and report them, in accordance with global regulatory reporting

requirements. If safety issues arise, Biomore works closely with regulatory authorities to communicate with physicians and patients.

#### **Research collaborations**

To tackle the rising complexity of drug discovery, development and clinical testing, Biomore collaborates closely with cross-disciplinary clinicians, physicians and academics in the public and private sectors, such as the Institute of Bioengineering and Nanotechnology, National University of Singapore, Singapore Health Services and Singapore Cancer Syndicate.

This provides access to novel drug targets, biomarkers, animal models and technological innovations that can broaden and diversify in-house research capabilities. Approximately 50% of Biomore's R&D pipeline comes from external sources, including research collaborations, licensing agreements, joint ventures and mergers and acquisitions (M&A). Some of Biomore's programmes were even transferred to academic and institutional laboratories to benefit from greater flexibility and government funding. These partners benefit in turn through funding, as well as Biomore's extensive resources, know-how and networks.

Biomore also partners with contract research organisations, which comprise specialist teams that typically handle specific segments of R&D work on a contract basis, such as toxicology studies.

#### **Scientific contributions**

In addition to producing pipeline products, Biomore also works pre-competitively with other researchers through scientific consortia, helping to address complex challenges that are of mutual interest to all parties, such as developing new economic models to promote antibiotic innovation. These consortia involve other pharmaceutical companies, academia and public health organisations. Biomore also strives to advance science and patient care by providing drugs and vaccines to external investigators for peer-reviewed research. Biomore's researchers also contribute to the scientific community by publishing hundreds of scientific papers in leading peer-reviewed journals every year. To aid in the search for effective treatments, the company is also committed to sharing the results of its clinical trials, regardless of their outcome, and submits relevant information to the authorities and the public. In 2018, Biomore submitted 153 manuscripts on its clinical trial results and other related papers. It also has multiple clinical trial databases containing highly valuable trial data, which it shares with the clinical research community on a case-by-case basis.

#### Manufacturing and supply chain

#### Manufacturing

Biomore's manufacturing sites span the globe, forming an integrated network with its parent company's other regional operations, along with external manufacturers that provide specialised expertise in different types of manufacturing processes. This strategy has been effective in broadening access to local markets worldwide. Globally, approximately 8,000 stock keeping units (SKUs) were manufactured in 2018, along with 213 million doses of human vaccines and over 100 billion doses of animal vaccines.

The upgrade of Biomore's manufacturing operations is a constant and ongoing process, reflecting advancing technology as well as continuing shifts in global healthcare needs. To reduce cost and increase capacity to meet growing demand, core areas of focus have included improving asset utilisation, technology modernisation, cybersecurity, outage resiliency as well as the introduction of data systems and innovative digital and analytics technologies.

All of Biomore's global manufacturing sites and those of its suppliers and partners must comply with the Current Good Manufacturing Practices (CGMPs), which are enforced by the US Food and Drug Administration. In addition, Biomore in Singapore must comply with the Good Manufacturing Practice Standard and Good Distribution Practice Standard, which are enforced by Singapore's Health Sciences Authority. These standards include requirements for handling raw materials, manufacturing, storage, logistics and distribution of products. All manufacturing facilities undergo regular inspections that are carried out by international health authorities in their respective jurisdictions. Internal quality testing is also carried out throughout the manufacturing process.

#### **Contract manufacturing organisations**

Globally, Biomore has over 140 manufacturing partnerships with contract manufacturing organisations. These arrangements offer the valuable benefits of costeffective scalability and flexible production. This is particularly useful for small-batch production during the early phases of R&D, such as pre-formulation, stability studies, trial batches and registration batches, limiting Biomore's financial exposure in case drugs fail during the large-scale Phase III trials. However, the large-scale manufacture of approved biologics and biosimilars is generally retained in-house to limit Biomore's risks, especially in terms of quality, intellectual property exposure and accountability.

All partners who supply active pharmaceutical ingredients, formulated products and sterile products are required to comply with Biomore's policies as well as the relevant regulatory requirements and guidelines. These requirements extend to the partner's own supply chain as well. As part of due diligence, Biomore conducts regular audits on its manufacturing partners. Quality testing is also conducted throughout every part of the supply chain, encompassing products manufactured internally as well as those purchased from partners.

#### Supply chain

Biomore's supply chain includes contract research organisations, contract manufacturing organisations, suppliers, cold-chain logistics specialists, distributors and more. The company's policies promote a diverse range of suppliers from different countries in order to promote a stable supply and avoid disruption arising from geopolitical events.

To ensure a lean and efficient supply chain, the company engages in end-to-end supply planning, which involves ensuring a high degree of interoperability among various parts of its supply chain. This allows for better demand planning. Moreover, delays in part of the supply chain can be adjusted for in subsequent parts of the supply chain. Biomore is currently assessing the use of blockchain to enable real-time supply chain visibility to further minimise its risk exposure.

Ensuring the safety, efficacy and quality of its products is an ongoing priority for Biomore throughout every stage of the value chain. As with all of Biomore's partners who supply active pharmaceutical ingredients, formulated products and sterile products, suppliers are regularly audited to ensure compliance with the relevant local and international regulatory requirements and guidelines, as well as Biomore's own policies.

Biomore's policies also contain strict supply chain guards to combat ingredient and drug counterfeiting. These include proactive threat assessments on facilities and supply routes that are deemed to be at risk from cargo theft and other illegal activities, allowing Biomore to deter, detect and respond to incidents. To protect the distribution chain, drugs are only supplied to authorised distributors, who can be verified against a public register. Each SKU is also tagged with a unique serial number, allowing anyone along the supply chain to authenticate the package as a genuine Biomore product. Moreover, the company takes steps to educate the public on the importance of purchasing from authorised vendors, as well as the risks of counterfeit products.

#### **Distribution and exports**

Biomore's products are distributed in 140 countries. Its drugs are sold primarily to drug wholesalers, retailers, hospitals, clinics, pharmacy chains, government agencies, insurers, health maintenance organisations, pharmacy benefit managers, research organisations and other institutions, while its vaccines are sold primarily to wholesalers, physicians, distributors and government entities.

Like other pharmaceutical companies, Biomore's distribution network is highly complex and expensive for the end consumer. In fact, as much as 41% of the cost of drugs goes to intermediaries in the supply chain. While wholesalers buy from Biomore and sell to distributors and healthcare organisations, there are also pharmacy benefit managers who act on behalf of payers like pharmacies, hospitals, clinics and insurers

to negotiate discounts for bulk buying and also for preferred insurance coverage. Insurers in turn cover part of the drug cost for patients.

#### Innovation and IT

Biomore embraces innovation along every part of its supply chain, which enables the company to achieve lower costs, higher productivity, greater patient safety and faster time-to-market. Its networked IT Centres work together to harness artificial intelligence, information science, data science, mobility and bioinformatics to support drug discovery and development, as well as manufacturing, sales and distribution.

Biomore's software engineers are constantly modernising the company's IT infrastructure, data centre capabilities, supply chain management and cybersecurity. The IT Centre also leverages data and information science to support Biomore's R&D and manufacturing functions. This involves creating solutions for generating, storing, sharing and analysing big data.

#### **Artificial intelligence**

To aid in drug discovery and disease forecasting, Biomore recently acquired a stateof-the-art biomedical start-up company that uses natural language processing to automatically mine big data for new biological pathways and targets. Their technology utilises deep learning algorithms to study patterns and advanced modelling to inform artificial intelligence decision making. Key data points include diverse unstructured documents from a wide range of sources, such as journals and other publications, clinical trial data, patient records and patents. This has been an important trend in the biomedical industry.

#### Biobanking

To enhance the efficiency of clinical trials, Biomore uses archived biological samples from cryogenic storage facilities known as biobanks, which are maintained by hospitals, universities and other pharmaceutical companies. These include blood, sputum, biopsies and cells collected from clinically characterised volunteers, which is used to build human disease models.

#### Automation

While Biomore leverages artificial intelligence with automation to help test thousands of compounds and disease models in parallel, there remain some regulatory uncertainties surrounding the use of automation in biopharmaceutical manufacturing. Nonetheless, automation plays a crucial supporting role in Biomore's manufacturing sites, transporting materials between production lines and minimising manual interaction and user error. This lowers costs and ensures consistent product quality between batches.

#### Small-scale production and single-use technologies

Due to the nature of drug development, Biomore is relying increasingly on small-scale production lines and single-use technologies to test and optimise existing processes, develop new procedures, conduct pilot studies and manufacture personalised drugs. Single-use technologies paired with artificial intelligence offer the benefit of faster and more efficient production without sacrificing product quality. They can be used with mobile equipment to facilitate a plug-and-play shop floor with advanced sensors and tracking, giving Biomore extra production flexibility.

#### Industry 4.0 and big data

There is even more regulatory uncertainty surrounding the use of industry 4.0 technology in biopharmaceutical manufacturing. As a result, uptake has been slow across the industry. Nonetheless, Biomore is currently exploring the use of process analytical technologies and networked sensors to track production in its bioreactors, enabling its scientists to monitor quality during production. Process analytical technologies collect big data, which can be used to analyse, predict and simulate processes for optimisation, as well as to develop contingency measures in case of malfunction.

#### **Cold chain logistics**

Biologics are expensive, complex and highly sensitive to temperature changes and microbial contaminants. Advanced storage and delivery technologies are therefore required to maintain the integrity of Biomore's drugs. The company's supply chain partners are also introducing blockchain and distributed ledger technology, which enable Biomore to keep track of shipments and help ensure provenance at every point of the supply chain.

#### Article from "Asian Business Briefing" - November 2019

Note - this article was written and published before the coronavirus pandemic.

#### The rise and rise of Biopharmaceuticals

The Biopharmaceutical industry is by far the fastest growing segment of the pharmaceutical industry. It was worth US\$238.2 billion globally in 2018, and it is projected to grow at a compound annual growth rate (CAGR) of 12%, reaching US\$526.6 billion by 2025.

Biopharmaceuticals are manufactured from biological substances, such as proteins, DNA and sugars. These are extracted from living organisms including humans, animals, plants and fungi. They often provide more effective treatment for a number of diseases than traditional pharmaceuticals and users experience fewer side effects. Biopharmaceuticals are used in treatments for cancer, cardiovascular, metabolic and neurological diseases; and genetic disorders.

Because biopharmaceutical products offer a safe and effective way to treat conditions that were previously untreatable, strong global demand has driven significant profits for biopharmaceutical companies, who are able to command high prices. The world's top 15 pharmaceutical products generate annual revenues of more than US\$2 billion each. Some even generate more than US\$10 billion a year.

#### Global markets

Globally, North America held 33% of the biopharmaceutical market in 2020 and is expected to remain the largest player for at least the next five years thanks to its strong healthcare infrastructure, rapid technological advancements and ageing population. The European Union is the second largest market. Between 2014 and 2020, 155 new biopharmaceutical products were registered in the United States and European Union.

The Asia Pacific Biopharmaceuticals market is the third largest market and is expected be worth US\$36.57 billion in 2020 and this is expected to grow by 10.05% per year.

#### **Drivers of growth**

Patient need is a key growth driver, with lethal diseases surging amid ageing societies. In 2018 alone, new cancer cases numbered 18.1 million, and new HIV-positive patients numbered 36.9 million across the globe. Moreover, there is a growing middle class with higher disposable income and greater awareness of biologic treatment options. More patients can afford high-quality healthcare than ever before.

These factors have driven a spike in R&D investments, especially in biosimilars and cancer drugs, paving the way for important scientific advances such as targeted therapy, drug personalisation and other genomic innovations that have led to the discovery of novel treatments and vaccines.

#### Major industry trends

Globalisation has been a key trend shaping the global biopharmaceutical industry. North America and Europe are still expected to remain the largest players for the next five years at least, though the industry is growing rapidly in Asia-Pacific (APAC). Demand is skyrocketing in the APAC region, though unpredictable regulatory environments and quality control issues remain significant hurdles.

The regulatory environment in APAC is beginning to move towards global standards, making it easier and faster than ever to register, market and sell drugs to payers in new markets in the region. This has also translated to a shorter time lag between product launches in the US/Europe and APAC, enabling biopharmaceutical companies to recoup their investments faster to fund their ongoing product pipeline.

Biopharmaceutical companies are also spending more – not just in absolute terms, but also as a percentage of total sales. This may be attributed to the rising cost of drug discovery, design, production and distribution as competitors race to optimise their operations, deliver higher quality products and shorten time-to-market. Technological advances such as data analytics, artificial intelligence and blockchain are now playing important roles in the biopharmaceutical value chain, as are bioprocessing innovations and high-tech tools such as genomic mapping, computational modelling and molecular imaging. Other strategic decisions leading to enhanced labour and asset efficiency, better process technology and more efficient supply chains have also paved the way to leaner, agile and more efficient discovery, production and distribution. However, these developments come at a significantly higher cost.

To minimise financial exposure, there has also been an increasing reliance on contract research organisations and contract manufacturing organisations, which have grown in size and scope to cover all parts of the value chain. Their strategic capabilities offer biopharmaceutical companies the benefit of greater operational flexibility and efficiency. To mitigate the rising cost of innovation, the industry is also seeing a rising number of strategic collaborations between private, academic and government research groups, and even between competitors.

#### **Opportunities and challenges**

There are, of course, significant challenges in the industry. Foremost is the rising cost of R&D and bioprocessing. Large-molecule biologics are already expensive to produce at an industrial scale, as new classes of molecules each require novel approaches to production, distribution and quality assurance. As cell therapies advance, biopharmaceutical companies are also seeing a rise in personalised medicines that need to be quickly produced in small batches. Setting up the novel technologies and processes required to manufacture them comes at significant cost.

At the same time, biopharmaceutical companies are under increasing pressure to lower prices as healthcare systems struggle to balance medical inflation and rising demand in the face of flat or even declining budgets. Customers like insurance companies, healthcare organisations and even patients may find it difficult to justify drug costs that can amount to US\$100,000 per year. There is also competitive pricing pressure coming from the growth of biosimilars, which are biologics proven to be highly similar versions of an existing biologic that has already received regulatory approval. On average, biosimilars cost 27% less than biologics for payers, making them a more attractive treatment option.

Regulatory scrutiny has also been intensifying. This is another significant challenge for biopharmaceutical companies, which received an unprecedented number of warnings over the last five years. Moreover, each market is governed by a specific regulatory regime, giving rise to increasing regulatory complexity and multiple quality standards as new markets open up to biopharmaceutical companies.

The rise in technological innovation has been accompanied by a rise in cyberattacks, with Merck, Roche and Bayer having all been hacked in recent years. As connectivity and automation become more entrenched in drug discovery and production processes, cyberattacks could potentially shut down global operations and compromise highly valuable proprietary research, clinical data, pharmaceutical intellectual property (IP) and new technologies. It could also expose patient information, which could erode consumer trust and threaten lucrative mergers and acquisitions, leading to massive revenue losses and plummeting share prices. Cybersecurity is thus a growing focus for biopharmaceutical companies.

Moreover, biopharmaceutical companies are exposed to significant reputational risks because the high price tag on biologics forms an insurmountable barrier for much of the global population. The industry's main players balance out this risk by introducing strategic initiatives primarily in developing countries, such as sub-Saharan African countries, where the population continues to struggle with health problems long since resolved in developed countries. These include donations, grants, shared resources and initiatives to improve access to medicines and vaccines and expand that market's manufacturing capacity. Large biopharmaceutical companies also codify their commitments to driving efficiency and reducing environmental impact to promote sustainability, training employees and promoting global diversity, as well as ethics, integrity and human rights in corporate governance.

#### Briefing note to the Board of Directors from the Production Director explaining the technology used in production including artificial intelligence and blockchain

To: The Board of Directors, Biomore From: Thanh Bui, Production Director, Biomore Subject: Use of artificial intelligence and blockchain in production Date: 03/02/2021

#### Introduction

This briefing note seeks to explain how artificial intelligence and blockchain is currently used in Biomore's production processes. It is intended to form the basis for discussion at the next Board meeting as we explore their further use in our supply chain and distribution operations.

#### Artificial intelligence

Artificial intelligence is currently used in our production processes in a number of areas:

- assisting with the intelligent transportation of materials between production lines reliably, and with the minimum of human intervention
- testing and interpreting test results for batches of production
- facilitating the early adoption of small-scale production, single use technologies and the automated production of personalised solutions.

Artificial intelligence is also used in our R&D pipeline to assist with the analysis of often unstructured data to inform our research programmes, such as the interpretation of customer questionnaires and mapping individuals to diagnostic reference groups. These pre-production applications are not considered further here.

#### Blockchain

Blockchain is essentially a public ledger where entries need to be approved by other parties to that blockchain.

Blockchain is used presently in our research pipeline, to coordinate input from our research partners, via the use of 'smart contracts'. Our service level agreement requirements are stated on a blockchain, which our collaboration partners then update as they progress. We acknowledge this progress on the blockchain once we have confirmed it. We also often use blockchain to transfer ownership of intellectual property once contractual terms have been fulfilled and funds paid/received. However, Blockchain is currently not used extensively in production.

#### Automation

Automation is used in production processes extensively for consistency and quality reasons. artificial intelligence and machine learning help to improve the flexibility of automation, allowing production control with the minimum of human intervention. For example, automatically adjusting for minor quality issues.

I look forward to discussing this with you further, in due course.

Best wishes

Thanh Bui

**Production Director** 

#### Article from "The Singapore Courier", 2 April 2021

#### **Biopharma and coronavirus**

The Coronavirus pandemic has disrupted many industries, including the all-important BioPharma sector, which is one of the pillars of the government's industrial strategy. We caught up with Dr Benjamin Ng, CEO of Biomore to discuss the impact the pandemic had on his company.

We started by asking him about the impact on the operations of the company.

"We were prepared for a big adverse event to some extent", he told us. "Biomore has a series of contingency plans in place to protect the company and its stakeholders in the event of an exceptional risk such as a global pandemic. When the scope of the COVID-19 crisis became apparent and Singapore's circuit-breaker measures were rolled out, Biomore was well prepared to implement the relevant contingency measures in Singapore and across the globe. The most urgent of these focused on protecting employees by transitioning to work-from-home policies where feasible; maintaining a steady supply of medicines and vaccines to patients who need them; continuing to support patients still involved in clinical trials; and reassuring payers regarding supply.

Although Biomore's production sites experienced inevitable disruption due to the circuit-breaker measures in Singapore and other lockdown measures across the globe, distribution delays were kept to a minimum thanks to the company's emergency ingredient and product stockpiles, which it maintains as part of its risk management strategy. Biomore is focusing on further optimising its manufacturing capacity so that it can replenish its stockpiles without undue disruption to its product pipeline."

But surely a health pandemic presents an opportunity to a Biopharmaceutical company?

"It gave us an opportunity to help society, not in a selfish way, but to genuinely use our skills to help out as this awful virus appeared. As lockdown measures devastated the world economy, biopharmaceutical companies worldwide raced to develop new vaccines and novel drugs, as well as to deliver much-needed supplies to the world's overtaxed hospitals. This resulted in unprecedented levels of cooperation between Biomore and our competitors as we shared data and assets, as well as development and manufacturing capabilities in order to put patient needs first. We managed to get one of our new products, Tiotryollate, through clinical trials, and launched this product in many countries. The product has been very popular as it alleviates the symptoms of COVID-19 in some patients, even though it was developed for other purposes. "

#### What about developing a vaccine against COVID-19?

Biomore has taken the decision not to develop our own vaccine. We believe that some of our global competitors are much better placed than we are in this respect. Our efforts in respect of Covid are focussed on relieving the symptoms of the illness.

#### What was the overall impact on Biomore's business?

"It's been mixed. I mentioned the success we had with our new respiratory drug Tiotryollate, which has provided us with an unexpected boost to sales. Other products have suffered to some extent. In the first global wave of the pandemic, COVID-19 resulted in severely limited access to hospitals and delayed medical procedures, causing Biomore's sales to fall 6% below budget. This was in the quarter starting 1 April 2020. Our biggest product, Pembrolumab, a blockbuster cancer drug saw a drop in new patients starting treatment, while vaccine sales dropped due to lockdown orders and fewer clinic visits. In the next quarter, starting 1 July 2020, sales spiked, increasing 15% compared to the previous quarter, as many health providers stockpiled drugs in anticipation of further disruption to supply chains. Since 1 September 2020, our manufacturing and sales have been back to normal before the second spike set in at the end of the year 2020 and into 2021. We were budgeting for a 30% increase in revenues for the year to 31 March 2021. It looks like our actual revenues will only have grown by a small percentage year on year, and that is all down to the pandemic."

# Biomore is well known for its research and development. Were you able to continue this during the pandemic?

"Drug discovery work and clinical trials were put on hold by various lockdown measures, disrupting Biomore's product pipeline and potentially threatening future product roll-out targets. Some existing clinical trial data was compromised by the

pandemic. With healthcare systems across the globe remaining under enormous strain, Biomore is taking stock of its position and developing contingency plans for its upcoming product launches over the next 12 months. "

#### What are Biomore's plans for the recovery?

"Part of our plans include exploring options for optimising drug discovery, including potential acquisitions and partnerships with smaller biopharmaceutical companies. Biomore is also tackling the challenge of how and when to restart its clinical trials as well as how to handle potentially compromised data. Telemedicine, travelling nurses and sending drugs directly to clinical trial patients could be innovative ways to continue drug trials on a wider scale outside of a medical setting.

Inevitably, the COVID-19 crisis highlighted inefficiencies in Biomore's supply chain, including over-reliance on intermediates and raw ingredients from certain regions. This was the case on the part of Biomore as well as its ingredient suppliers and production partners. Further disruptions in those key regions could have severe knock-on effects throughout Biomore's supply chain. The company is thus auditing its supply chain and evaluating the need to diversify its suppliers further. This would avoid over-reliance on any single supplier or production region, while giving Biomore the flexibility to adapt to unforeseen circumstances.

As hospitals and clinics across the globe begin keeping more drug stock on hand in case of potential supply chain disruption, Biomore is planning ahead for spikes in demand in order to avoid undue pressure on its production and supply chain."

#### What impact will the pandemic have on Biomore in the longer term?

"The COVID-19 pandemic will inevitably leave a lasting mark on Biomore as well as the healthcare industry as a whole. Given the industry's current momentum, Biomore's increased R&D spend on vaccines and prevention is likely to continue in the longer term. In anticipation of sudden fluxes in demand, the company is also investing more heavily into flexible and vertically scalable production capabilities, both by enhancing its internal capabilities and through contract manufacturing partners.

To hasten drug discovery, Biomore is also stepping up its efforts to mine data about diseases and treatment through artificial intelligence. Within the biomedical industry, the pandemic has yielded a deeper level of collaboration and faster joint innovation in terms of R&D and manufacturing. Some competitors are even collaboratively developing unbranded treatment products. This reduction of organisational silos could well extend beyond the pandemic as the benefits become more apparent in the long run.

Remote work has also transformed Biomore's operations. Many sales representatives are conducting online meetings with their clients, significantly lowering the sales budget. There has also been a shift to fewer onsite employees at Biomore's production sites, enhanced by a greater degree of automation and manufacturing platforms with more flexibility. Some clinical trials are also being conducted remotely or digitally. This model has the advantage of being more convenient for clinical trial patients while also opening up deeper candidate pools for Biomore. These measures could well constitute deep and lasting changes for the company and its employees."

#### Extract from Minutes of Board of Directors' meeting - 4 April 2021

#### Manufacture of Abroxanib

Given final regulatory approval of Abroxanib is imminent, discussion turned to the manufacturing process for the remaining 10-year patent period.

Mr Bui, the Production Director noted that the production process will involve the use of customised bioreactors. The required equipment does exist and is used mainly by Armstrong Biologics Co (ABC), an American firm. Equivalent reactors could be built by Biomore but would be expensive. In addition, Mr Bui noted ABC's patented accelerated fermentation process that would speed up production times and so reduce costs.

Mr Wong, Sales and Marketing Director expressed concern that ABC had a quality related incident a few years ago and said that inhouse development of the required process could in any case be exploited elsewhere by Biomore.

The Board agreed to commission a separate report on ABC from an industry consultancy, and to consider the financial and non-financial aspects of a potential joint venture further before discussing it again at next month's meeting.

#### Restructuring

Dr Ng confirmed that, as discussed at the last meeting of the Board, he has commissioned Alpha Consulting to look into the organisational structure of Biomore and suggest a restructuring, given the Covid-19 Pandemic response is showing an increased need for product specialisations that are focussed globally. There is therefore a concern that the current functional structure may no longer be fit for purpose. Their report will be received next month, and he said he will have it sent to all members of the Board as soon as it arrives.

If a restructuring does take place, this may mean redundancies need to be made in the workforce. In order to be transparent, it was agreed that if a restructuring is required, it would be announced to all those affected in July 2021, and implemented by 30 June 2022.

#### Exhibit 9

#### Consultants' report: Armstrong Biologics Co.

To: The Board of Directors, Biomore Ltd

From: BioPharm Consultancy (BPC)

Subject: Armstrong Biologics Co

Date: 21/05/2021

#### Introduction

As requested, this report provides background analysis of Armstrong Biologics Co (ABC), for the Board to use in considering the suitability of ABC as a potential business partner.

#### Background

ABC (Nasdaq: ARMB) is priced at US\$35.50 per share with a market capitalisation of equity of US\$9.5 billion. ABC's headquarters and some research facilities are located in California, USA. The business was founded in 1997 by Simon Armstrong, who was a lead biopharmaceutical researcher at Stanford University, and James Calfwitz, a pharmaceuticals engineer.

The key focus of the business is the cost effective, high quality, high volume production of biopharmaceuticals.

#### Operations

ABC has its major manufacturing site in South Korea, which houses 10 custom built 15,000 litre mammalian cell culture bioreactors.

ABC has invested significantly over the years in increasing the pace of production through an accelerated fermentation process. This reduces the production time significantly and therefore the cost. This process is patent protected for many years to come.

#### Ownership

Shares in ABC are widely owned. No one shareholder holds more than 5%, with the exception of the two founding members, who still own 15% each. Significant loans contain covenants relating to gearing levels, interest cover and dividend pay-out ratios.

#### Financial performance and position

The industry compound annual growth rate (CAGR) for biological manufacturers is typically estimated at around 9% per year. ABC has returned a revenue CAGR of close to 25% per year over the last 3 years, with this trend expected to continue for the foreseeable future.

Turnover in 2019, the last year of 'typical' operations pre-pandemic – was US\$11 billion, with EBITDA of US\$3.5 billion. In addition to the US\$9.5 billion of equity by market value, ABC has US\$4.5 billion of long-term debt finance, maturing in the range of 2-10 years. Within this profile, a large syndicated bank loan for US\$3 billion becomes repayable in 5 years' time.

#### **Business model**

Typically, ABC partners with biopharmaceutical research companies. The research company usually provides a master cell bank, which ABC then takes into large scale production. ABC produces both patent-protected biologics and biosimilars for a range of partners at any one time. The route from ABC to the patient is varied. Sometimes the research company manages the downstream distribution – often through wholesale to the major distributors. ABC never takes responsibility for distribution.

Increasingly artificial intelligence is used by ABC to monitor the production process and to interpret test results. Business partners have access to production data through ABC's secure extranet facility for their own monitoring purposes.

#### Reputation

ABC has all the required certification in place and has clean inspection reports going back for 3 years in all its theatres of operation. There was unfortunately one incident 4 years ago which resulted in a virally contaminated batch being released. This was detected downstream and no patient was endangered, but at the time this prompted a detailed review by the Food and Drug Administration in the USA. This involved disrupting production at the main plant for nearly 6 weeks, and damaged ABC's reputation in the industry. The source of the contamination was attributed to a faulty cleaning procedure. The viral detection process was also reviewed and improved as a result. There is no reason to suppose this issue would recur.

#### Disclaimer

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Please do not hesitate to contact us if we can be of any further assistance

Best wishes

**BioPharm Consultancy** 

#### Report

To: The Board of Directors of Biomore Pte Ltd

From: Alpha Consulting

Date: 31 May 2021

#### Introduction

We have reviewed the current structure of Biomore Pte Ltd. Given the increasing complexity of the biopharmaceuticals industry, companies operating in isolation are finding it less feasible to operate successfully. The changes to the industry, that have already been taking place over the last decade have been accelerated by the coronavirus pandemic. These include the demand for more complex medicines, greater cooperation with external parties in the development and manufacturing of new products, and demand for customised medicines. It is therefore crucial for Biomore to implement a leaner structure that will be more appropriate for the future.

We are therefore proposing the following changes:

- 1. Reduce the size of the discovery department and make greater use of research collaborations with external partners and outsourcing of activities. The discovery department role would focus on coordinating the activities of the various partners. Biomore has already increasingly used such collaborations, for example the collaborations with universities. As consumers demand ever more complex remedies, the discovery process has become much more challenging and it is difficult for a single team within one company to have sufficient expertise. Universities can also take advantage of government incentives that are not available to private companies.
- 2. Reduce the size of the clinical trials department by 50%. More clinical trials can be outsourced, particularly those taking place outside of Singapore.
- 3. Replace the current functional structure with a matrix structure. Staff in all departments other than purchasing would be allocated to one of several product groups: Pharmaceuticals respiratory, Pharmaceuticals oncology, Pharmaceuticals diabetes, Vaccines respiratory, Vaccines other infectious diseases, Animal health and Digital solutions. The benefits of forming such

product groups are that staff from all departments will have a better understanding of the priorities of the other departments - for example, the sales teams will understand the complexities of developing particular drugs, and the R&D department will be able to prioritise their work better after understanding the commercial situation faced by the sales department.

4. Centralise the purchasing department - the purchasing department will be centralised globally and will not form part of the matrix structure. Having one single purchasing department will enable the company to diversify its suppliers to reduce the risk of shortages. It will also enable the company to negotiate better deals with suppliers.

The new structure can be shown as follows:

	Board of Directors						
	Chief Executive Officer						
	Pharma respiratory	Pharma oncology	Pharma diabetes	Vaccines respiratory	Vaccines other infections	Animal health	Digital solutions
Research & development							
Production							
Sales and marketing							
Information							
technology Finance							
Legal							
Human							
resources							

Should you decide to go ahead with this proposal, we would be happy to advise on the implementation of the project.

Yours sincerely,

Alpha Consulting

#### Suggestions for further research and reference list

#### Further research

The following resources may be useful when beginning your research into the case study company. As always, the caveat is to read everything with a healthy dose of scepticism and apply professional judgment. Just because an article is on this list, does not give it legitimacy or relevance. All links were active as at 19 November 2020.

#### Articles and information:

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