

PRESTIGE BIOPHARMA LIMITED

Business Report 2021



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*“PRESTIGE BIOPHARMA LIMITED
PIONEERS BIOTHERAPEUTIC AND
VACCINE DEVELOPMENT
RESEARCH WITH THE AIM OF
FINDING CURES AND
PREVENTATIVE MEDICINES FOR
DEVASTATING DISEASES,
AND TO PROVIDE THE ESSENTIAL
ACCESS TO AFFORDABLE
QUALITY BIOLOGICS
TO THE PATIENTS OF THE WORLD.”*

Who we are

Headquartered in Singapore and listed in South Korea, Prestige Biopharma Limited is a biopharmaceutical company specialising in the discovery and development of biosimilars and new antibody drugs.

We have recently reported on the addition of vaccine therapies into our pipeline, collaborating with partner companies in the development and commercial production of vaccines to defeat COVID-19 as well as lay the foundation for defence against future vaccine treatment needs.

Total Assets (USD)
as at 30/06/2021

535 million

Market Capitalisation (USD)
as at 30/06/2021

1.75 billion¹⁾

Development Pipelines

10 Pipelines

Patent Technologies

9 Platforms

Vaccine Production Capacity


104,000 ℓ

Global Partnership

46 countries

1) Translated into USD at the market average exchange rate as at 30/06/2021, announced by Seoul Money Brokerage Services, Ltd.

History

- 
- 2021.06 ○ PBP1510 phase 1/2a clinical trial initiation approved in France
 - 04 ○ Participation in Sputnik COVID19 Vaccine CMO Consortium
 - 04 ○ Establishment of Prestige Biopharma Korea
 - 03 ○ Establishment of Advanced Research Center (ARC) in Boston, USA
 - 02 ○ IPO on the Korea Composite Stock Price Index (KOSPI)
 - 2020.11 ○ EU EMA ODD approval for pancreatic cancer drug (PBP1510)
 - 07 ○ Korea MFDS ODD approval for pancreatic cancer drug (PBP1510)
 - 06 ○ US FDA ODD approval for pancreatic cancer drug (PBP1510)
 - 2019.06 ○ Avastin biosimilar (HD204, Bevacizumab) phase 3 clinical trial initiated
 - 04 ○ Herceptin biosimilar (HD201 Trastuzumab) Marketing Authorization Applications (MAA) submitted to EU EMA
 - 04 ○ Herceptin biosimilar (HD201, Trastuzumab) phase 3 interim Clinical Study Report (iCSR) completed
 - 2015.07 ○ Establishment of Prestige Biopharma Limited

CEO Reflections



Prestige Biopharma Limited (PBP) has been laying a solid foundation for future growth for the past six years since its establishment in 2015.

The Company is currently participating in the CMO consortium to produce Russia's Sputnik COVID-19 vaccines. Our vaccine centre with 104,000 litres of final production capacity has started a test operation and the commercial production of Sputnik vaccine is scheduled to commence in the fourth quarter of 2021, and strong sales and earnings are expected from the vaccine CMO business.

We expect commercialisation of our biosimilar pipelines next year. PBP's Herceptin® biosimilar, HD201 has secured global distribution partnerships in major regions of the world, and it is currently under EU EMA's review. The FDA bridging study of HD201 was published in the international journal of Pharmacology Research & Perspectives last July and the US submission to FDA is on target to be completed this year. PBP's biosimilar to Avastin®, HD204 is in the process of the global Phase 3 clinical trial and PBP1502, biosimilar to Humira® is in the preparation of its Phase 1 clinical trial.

The initiation of Phase 1/2a clinical trial of PBP's first-in-class antibody treatment of pancreatic cancer, PBP1510 was approved in France in June this year.

Based on this fundamental strength, the Company will see a solid growth momentum from the fourth quarter this year.

Prestige Biopharma

Highlights in FY2021



IPO / February 2021

Prestige Biopharma Limited (KOSPI: 950210) successfully completed its IPO on the Korean Stock Exchange in February 2021.



Vaccine Centre / March 2021

Prestige Biopharma's vaccine centre with 104K ℓ of production capacity commenced construction in Korea.



Busan R&D Centre / May 2021

The Company and Busan City entered into an MOU for the establishment of Research and Development (R&D) centre in Busan, South Korea.



PBP1510 Phase 1/2a / June 2021

France has approved a Phase 1/2a clinical trial of our first-in-class anti-PAUF monoclonal antibody, PBP1510, for the treatment of pancreatic cancer.

Business Overview

Prestige Biopharma Limited specialises in the development of biosimilars, antibody biologics and COVID vaccines with its global offices and R&D centers in Singapore, Korea, Australia, Belgium and USA.

The Company pioneers biotherapeutics research to find cure for devastating diseases and to bring affordable quality biologics to the world.

“INNOVATION FOR LIFE”

Key Business

High Quality &
Cost Competitive
BIOSIMILAR



TUZNUE®
(Herceptin®
Biosimilar)



VASFORDA®
(Avastin®
Biosimilar)

First-in-Class
**ANTIBODY
DRUG**



PBP1510
Anti-PAUF
Antibody for
Pancreatic
Cancer



ODD Grand Slam

Global-scale
Manufacturing
VACCINE

- COVID-19 vaccine manufacturing to contribute to the high global demand
- Total production capacity of 104,000L in 2,000L batch scale
- Development of next generation vaccines



Business Overview

BIOSIMILAR

Our first biosimilar pipeline's commercialisation is expected next year. The Company's Herceptin® biosimilar, HD201 has secured global distribution partnerships in major regions of the world, and it is currently under EU EMA's review. The FDA bridging study of HD201 was published in the international journal of Pharmacology Research & Perspectives last July and the US submission to FDA is on target to be completed this year.

The second biosimilar to Avastin®, HD204, is in the process of the global Phase 3 clinical trial and PBP1502, the third biosimilar to Humira® is in the preparation of its Phase 1 clinical trial.

ANTIBODY DRUG



The initiation of Phase 1/2a clinical trial of first-in-class antibody treatment of pancreatic cancer, PBP1510 was approved in France in June this year. The European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA) and Korean Ministry of Food and Drug Safety (MFDS) granted Orphan Drug Designation (ODD) to PBP1510 last year and ODD products' marketing authorisation application can be reviewed before Phase 3 clinical trial depending on the result of Phase 2 study.

The Company's another first-in-class anti-CTHRC1 monoclonal antibody, PBP1710 is under later stage of cell line development.

Please refer to the next page for our pipelines' development summary.

Business Overview

Development Summary of Biosimilar and Antibody Drug Pipelines

Chemical name	Indication	Original (company)	Pipeline	Development	Pre-clinical	Phase 1 - Phase 3	EMA/FDA Submission
Trastuzumab	Breast cancer, Gastric cancer	Herceptin (Roche)	HD201 (Tuznue®)				<ul style="list-style-type: none"> - MAA Submitted to EU EMA - MAA Submitted to Health Canada - MAA Submitted to Korea MFDS
Bevacizumab	Solid tumors	Avastin (Roche)	HD204 (Vasforda®)				<ul style="list-style-type: none"> - Global Phase 3 Study Ongoing - MAA Scheduled to be Submitted to FDA / EMA in 2022
Adalimumab	Arthritis	Humira (Abbott)	PBP1502				- Phase 1 Study Scheduled to be initiated
Anti-PAUF	Pancreatic cancer	First in Class	PBP1510				- Phase 1/2a Study IND approved in France
Denosumab	Bone loss, Osteoporosis	Prolia (Amgen)	PBP1601				- Under preparation of Pre-clinical trial: Master Cell Bank (MCB) / working cell bank (WCB) Development
Aflibercept	Macular edema, Metastatic colorectal cancer	Eylea (Regeneron)	PBP1602				- Under preparation of Pre-clinical trial: Master Cell Bank (MCB) / working cell bank (WCB) Development
Eculizumab	Atypical haemolytic uremic syndrome	Soliris (Alexion)	PBP1603				- Under early stage of cell line development
Ipilimumab	Metastatic / Unresectable melanoma	Yervoy (BMS)	PBP1701				- Under later stage of cell line development
Anti-CTHRC1	Solid tumors	First in Class	PBP1710				- Under later stage of cell line development
Pertuzumab	Metastatic breast cancer	Perjeta (Roche)	PBP1801				- Under early stage of cell line development

Business Overview

VACCINE

Prestige Biopharma is participating in the CMO consortium to produce Russia's Sputnik COVID-19 vaccines. The Vaccine Centre with 104,000 litres of final production capacity has started a test operation in August 2021. The commercial production of Sputnik vaccine is scheduled to commence in the fourth quarter of 2021 and strong sales and earnings is expected from the vaccine CMO business.

The Company's global-scale Vaccine Centre, being built with its related company Prestige Biologics' patented technology ALITA Smart BioFactory™ in Osong, South Korea, will be equipped with 52 units of 2,000 litre single-use bioreactors.

Highlights of Vaccine Centre



✓ Full Single-Use System

- Enables mass production of vaccine in the short-term
- Reduced risk of cross contamination & increase in operational efficiency



✓ Customized Engineering Platform

- World's 1st digital AI based smart factory in bio-manufacturing
- Fast change-over when catering for multiple products and processes



✓ Digitally Enabled Lab & IoT Controlled

- Automated AI / machine-learning-enabled process parameter control
- Real-time trending with the data from factory to Digitally Enabled Lab

Corporate Governance

Board of Directors (the Board)

Our Board members have more than 30 years of experience on average. The Board is committed to helping the Company achieve long-term success. The Board provides direction to management by setting the Company's strategy and overseeing its implementation.

1. Park Soyeon

CEO / Chairman

2. Michael J. Kim

COO

3. Tay Lai Wat

CFO

4. Lee Kok Fatt

Independent Director

5. Jeon Kyunghee

Independent Director

6. Lee Eui Kyung

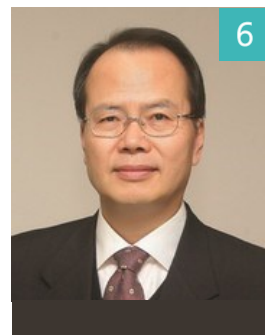
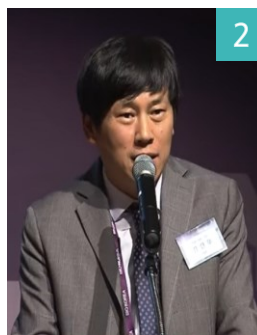
Independent Director

7. Bang Kue Ho

Independent Director

8. Oh Seung Joo

Independent Director



Corporate Governance

Board's Committees

The Board has four committees: Audit Committee, Nomination Committee, Remuneration Committee, Related Party Transactions Committee. Details of each Committee as at June 30, 2021 are as follows:

[As at June 30, 2021]

Committee	Composition	Key Responsibilities
Audit Committee	Lee Eui Kyung (Chairperson), Lee Kok Fatt, Jeon Kyunghee	<ul style="list-style-type: none"> ▪ Financial reporting and disclosure matters <ul style="list-style-type: none"> - Monitor the financial reporting process, - Review the Group's consolidated financial statements ▪ Internal controls <ul style="list-style-type: none"> - Review the adequacy and effectiveness of internal controls ▪ External auditor <ul style="list-style-type: none"> - Determine the criteria for selecting, monitoring and assessing the external auditor - Review and discusses the key audit matters
Nomination Committee	Lee Kok Fatt (Chairperson), Jeon Kyunghee, Lee Eui Kyung	<ul style="list-style-type: none"> ▪ Selection criteria and nomination process for Directors <ul style="list-style-type: none"> - Review the candidate ▪ Induction and Training for new Directors <ul style="list-style-type: none"> - Oversee the onboarding of new Directors
Remuneration Committee	Lee Kok Fatt (Chairperson), Jeon Kyunghee, Lee Eui Kyung	<ul style="list-style-type: none"> ▪ Director compensation <ul style="list-style-type: none"> - Oversee the remuneration of senior executives and directors, including making recommendations to the Board on the remuneration of executive directors
Related Party Transactions Committee	Jeon Kyunghee (Chairperson), Lee Kok Fatt, Lee Eui Kyung	<ul style="list-style-type: none"> ▪ Fair transaction regulations <ul style="list-style-type: none"> - Voluntarily comply with fair transaction regulations to enhance corporate transparency - Monitor the Group's related party transactions

Information on Shareholders

1. Ownership of shares by the major shareholders and related parties

[As at June 30, 2021]

Name	Relationship	Type of share	Ownership			
			Period start		Period end	
			Shares	Ratio (%)	Shares	Ratio (%)
Mayson Partners Pte Ltd	Major shareholder	Common	2,519,135	27.42	2,519,135	20.96
Park Soyeon	Executive member	Common	1,957,445	21.30	1,837,445	15.29
Michael J. Kim	Executive member	Common	1,901,890	20.70	1,781,890	14.83
Jeon Kyunghee	Independent director	Common	0	0.00	350	0.00
Total		Common	6,378,470	69.42	6,138,820	51.08

2. Matters related to the major shareholder

- 1) Name: Mayson Partners Pte Ltd (Exempt Private Limited Company)
- 2) Ownership of shares: Park Soyeon (50%), Michael J. Kim (50%)
- 3) Purpose of incorporation: Incorporated in 2019 to secure management rights
- 4) Financial statements for FY2021 (2020.07.01-2021.06.30)

(Unit: 1,000 USD)	Amount
Total Assets	108,441
Total Liabilities	1,942
Total Equity	106,499
Revenue	-
Net Loss	(1,388)

Information on Shareholders

3. Ownership of shares

A. Share Ownership Status

[As at June 30, 2021]

Classification	Name	Shares	Ratio (%)	Note
Shareholders with over 5% voting shares	Mayson Partners Pte Ltd	2,519,135	20.96	Major shareholder
	Park Soyeon	1,837,445	15.29	Executive member
	Michael J. Kim	1,781,890	14.83	Executive member
	Octava Fund Limited	1,820,748	15.15	-

B. Minority Shareholders

[As at June 30, 2021]

Classification	Shareholder			Shares owned		
	Shares-holders	Total Shares-holders	Ratio (%)	Number of Shares	Total Shares	Ratio (%)
Minority shareholder	58,400	58,407	99.99	3,297,761	12,019,231	27.44

Executives & Employees

1. Registered Executives

[As at June 30, 2021]

Name	Date of birth	Position	Degree & Career
Park Soyeon	January 1963	CEO	<ul style="list-style-type: none"> Ph.D. in Biochemistry, Univ. of Missouri-Columbia, USA Executive advisor, A*STAR Singapore (Previous)
Michael J. Kim	June 1964	COO	<ul style="list-style-type: none"> MBA, New York University, USA Managing director, Qion Pte Ltd (Previous)
Tay Lai Wat	October 1956	CFO	<ul style="list-style-type: none"> Bachelor of Accounting, Univ. of Stirling, Scotland CFO/COO, Singapore Shipping Corporation / Stamford Land Corporation Ltd (Previous)
Lee Kok Fatt	September 1973	Independent director	<ul style="list-style-type: none"> MS in Management, London Business School, England Deputy CEO, Gardens by the Bay (Current)
Jeon Kyunghee	March 1968	Independent director	<ul style="list-style-type: none"> Bachelor of Laws, Hanyang University, Korea Partner attorney, DR & AJU LLC (Current)
Lee Eui Kyung	December 1959	Independent director	<ul style="list-style-type: none"> Ph.D. in Business administration, Seoul National University, Korea Professor at Daejin University (Current)
Bang Kue Ho	August 1963	Independent director	<ul style="list-style-type: none"> Ph.D. in Microbiology, Chungnam National University, Korea Professor at Gyeongsang National University (Current)
Oh Seung Joo	July 1976	Independent director	<ul style="list-style-type: none"> Bachelor of Management, Indiana University Kelley school of business, Indiana, USA General manager, KB Securities Co Ltd (Current)

Executives & Employees

2. Employees

[As at June 30, 2021]

Division	Number of Employees ¹⁾		
	Permanent	Contract	Total
Business Development / Finance / HR / IT	22	2	24
Medical & Regulatory Affairs	23	1	24
R&D	39	2	41
Total	84	5	89

	Team	Degree			
		PhD	Master	Others	Total
R&D Professionals	Management & Operation	3	2	2	7
	Quality Assurance	-	2	1	3
	Technical & Operation Support	1	-	-	1
	Lab Management & Safety	-	1	1	2
	Development & Characterization	1	-	1	2
	Bioanalytical	-	1	6	7
	Bioassay	-	1	3	4
	Pharmacokinetic and Immunogenicity	7	4	3	14
	Clinical Development	6	5	11	22
	Total	18	16	28	62

1) The number includes the employees of Prestige Biopharma Korea and Prestige Biopharma USA Inc.

Affiliates & Subsidiaries

1. Affiliates

[As at June 30, 2021]

Classification	No. of affiliates	Name (Country)
Listed	1	<ul style="list-style-type: none"> ▪ Prestige Biologics Co Ltd (Korea, KOSDAQ-listed)
Unlisted	6	<ul style="list-style-type: none"> ▪ Prestige Biopharma Australia Pty Ltd (Australia) ▪ Prestige Biopharma Belgium BVBA (Belgium) ▪ Prestige Biopharma Korea Co Ltd (Korea) ▪ Prestige Biopharma USA Inc (USA) ▪ Qion Pte Ltd (Singapore) ▪ Mayson Partners Pte Ltd (Singapore)

2. Subsidiaries

[As at June 30, 2021]

Name (Country)	Incorporation	Business	Total assets (USD)	Ownership
Prestige Biopharma Australia Pty Ltd (Australia)	Apr. 11, 2018	Regulatory affairs	827,198	Wholly owned
Prestige Biopharma Belgium BVBA (Belgium)	Jun. 07, 2018	Clinical development	115,661	Wholly owned
Prestige Biopharma USA Inc (USA)	Mar. 25, 2021	R&D	5,033,733	Wholly owned
Prestige Biopharma Korea Co Ltd (Korea)	Apr. 21, 2021	R&D	18,428,984	Wholly owned

Financial Statements

Consolidated

1. Consolidated Statements of Financial Position

[As at June 30, 2019, 2020 and 2021]

<i>(USD)</i>	<i>June 30, 2021</i>	<i>June 30, 2020</i>	<i>June 30, 2019</i>
Current assets	407,023,791	41,485,283	17,349,278
Non-current assets	127,636,758	91,852,009	71,788,720
Total assets	534,660,549	133,337,292	89,137,998
Current liabilities	12,430,512	7,059,895	29,243,504
Non-current liabilities	13,415,298	11,511,461	9,500,691
Total liabilities	25,845,810	18,571,356	38,744,195
Share capital	525,727,248	127,241,958	53,198,489
Other capital adjustment	8,243,831	5,549,900	2,784,546
Other comprehensive income(loss) accumulated amount	(418,073)	205,724	99,768
Retained earnings(loss)	(24,738,267)	(18,231,646)	(5,689,000)
Total equity	508,814,739	114,765,936	50,393,803
Total liabilities and equity	534,660,549	133,337,292	89,137,998

Financial Statements

Consolidated

2. Consolidated Statements of Comprehensive Income (Loss)

[For the year ended June 30, 2019, 2020 and 2021]

<i>(USD)</i>	<i>2021</i>	<i>2020</i>	<i>2019</i>
Revenue	0	0	1,840,000
Gross profit	0	0	1,840,000
Operating expenses	(16,184,385)	(9,093,745)	(5,719,144)
Operating Profit(Loss)	(16,184,385)	(9,093,745)	(3,879,144)
Other Income	14,018,738	1,207,056	2,730,719
Other expenses	(377,379)	(5,059,593)	(41,400)
Financial income	949,665	833,094	323,487
Financial costs	(4,883,260)	(347,100)	(243,599)
Loss before income tax	(6,476,621)	(12,460,288)	(1,109,937)
Income tax benefit(expense)	(30,000)	(82,358)	(165,012)
Loss for the year	(6,506,621)	(12,542,646)	(1,274,949)
Other comprehensive income(loss)	(623,797)	105,956	97,891
Total comprehensive income(loss) for the year	(7,130,418)	(12,436,690)	(1,177,058)

Financial Statements

Company

1. The Company's Statements of Financial Position

[As at June 30, 2019, 2020 and 2021]

<i>(USD)</i>	<i>June 30, 2021</i>	<i>June 30, 2020</i>	<i>June 30, 2019</i>
Current assets	391,200,054	40,027,116	16,562,156
Non-current assets	144,488,838	91,267,266	72,432,782
Total assets	535,688,892	131,294,382	88,994,938
Current liabilities	14,025,266	6,781,876	29,199,895
Non-current liabilities	11,246,245	9,677,647	9,498,222
Total liabilities	25,271,511	16,459,523	38,698,117
Share capital	525,727,248	127,241,958	53,198,489
Other capital adjustment	8,243,831	5,549,900	2,784,546
Retained earnings(loss)	(23,553,698)	(17,956,999)	(5,686,214)
Total equity	510,417,381	114,834,859	50,296,821
Total liabilities and equity	535,688,892	131,294,382	88,994,938

Financial Statements

Company

2. The Company's Statements of Comprehensive Income (Loss)

[For the year ended June 30, 2019, 2020 and 2021]

<i>(USD)</i>	<i>2021</i>	<i>2020</i>	<i>2019</i>
Revenue	0	0	1,840,000
Gross profit	0	0	1,840,000
Operating expenses	(15,406,359)	(8,956,096)	(5,780,674)
Operating Profit(Loss)	(15,406,359)	(8,956,096)	(3,940,674)
Other Income	14,018,700	1,208,292	2,730,788
Other expenses	(377,379)	(5,059,593)	(41,400)
Financial income	1,037,489	966,070	381,054
Financial costs	(4,839,150)	(347,100)	(249,908)
Loss before income tax	(5,566,699)	(12,188,427)	(1,120,140)
Income tax benefit(expense)	(30,000)	(82,358)	(165,012)
Loss for the year	(5,596,699)	(12,270,785)	(1,285,152)
Total comprehensive income(loss) for the year	(5,596,699)	(12,270,785)	(1,285,152)

Public Disclosure (KRX/FSS)

Disclosure	Date
▪ Reporting of Sales, Operating income/loss or Net income/loss Changes by 30% or more	12/Aug/2021
▪ Correction of Quarterly Report (FY2021, Q3)	12/Aug/2021
▪ Acquisition of Patent Rights for 'Method for preparing antibody through regulation of sugar content of antibody' in Europe	21/July/2021
▪ Approval for PBP1510 Clinical Trial (Phase 1/2a) in France	18/Jun/2021
▪ Confirmation to Grant Voting Rights to Shareholders as at 30/June/2021 for Shareholders' Meeting	15/Jun/2021
▪ Decision to Make an Equity Investment on PBP Korea (KRW 61,490 million)	28/May/2021
▪ Decision to Make a Cash Loan to PBP Korea (KRW 61,490 million)	
▪ Quarterly Report (FY2021, Q3)	28/May/2021
▪ Acquisition of Patent Rights for 'Antibody specifically binding to PAUF and use thereof' in USA	26/May/2021
▪ Change of KOSPI Stock Name ('PB PHARMA' → 'PRESTIGE BIOPHARMA')	24/Feb/2021
▪ Report on Status of Specific Securities Owned by Executive Officers, etc. (Bang Kyu Ho)	18/Feb/2021
▪ Report on Stocks Held in Bulk / Report on Status of Specific Securities Owned by Executive Officers, etc. (Octava Fund Limited)	16/Feb/2021
▪ Report on Changes in Equity Shares of the Largest Shareholder	16/Feb/2021
▪ Report on Status of Specific Securities Owned by Executive Officers, etc. (Mayson Partners / Park Soyeon / Michael Jinwoo Kim / Jeon Kyunghee)	15/Feb/2021
▪ Report on Stocks Held in Bulk (Mayson Partners)	15/Feb/2021
▪ Report on Results of Issuance of Securities	28/Jan/2021
▪ Securities Registration Statement (IPO) / Prospectus	22/Jan/2021



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