



DISCLAIMER

The financial information in this document are consolidated earnings results based on K-IFRS.

This document is provided for the convenience of investors only, before the external audit on our Q4 2021 financial results is completed. The audit outcomes may cause some parts of this document to change.

This document contains "forward-looking statements", which are addressed based on our current business environment and strategies. Certain risks and uncertainties in the future, such as changes in business environment and strategies, may cause actual results to be materially different from those expressed in this document.







Record High Earnings 4,509

Operating Profit 2,539

- * Accrued in 2021
- Revenue 9,290
- Operating Profit 4,742 (KRW 100Mn)



GBP510 in Phase 3: Serology in progress

61% of clinical serum sample collected

MFDS approval expected in 1H 2022



Next-gen Universal Vaccine against Pandemic

Secured \$50Mn funding from CEPI for early-stage development (incl. Phase 1/2) of next-gen vaccine against pan-respiratory virus, Sarbecovirus



for 2023 contract



(1) Income Statement



SK bioscience has achieved the record-high quarterly and full-year financial result, majorly driven by revenues from CMO drug substance (DS) manufacturing

(unit: KRW 100Mn)

Financials	4Q20	3Q21	4Q21	YoY	QoQ
Revenue	670	2,208	<u>4,509</u>	573%	104%
COGs	363	894	1,684	-	-
Gross Profit	307	1,314	<u>2,825</u>	820%	115%
(%)	46%	60%	63%	+17%p	+3%p
SG&A expenses	198	310	286	-	-
Operating Profit	109	1,004	<u>2,539</u>	2,230%	153%
(%)	16%	45%	56%	+40%p	+11%p
Non-operating profit & loss	∆3	∆38	∆23	-	-
Profit before Income Tax	106	966	<u>2,516</u>	2,275%	161%
Income tax	8	202	676	-	-
Net Profit	98	764	<u>1,840</u>	1,778%	141%

2020	2021
2,256	9,290
1,303	3,587
953	5,703
42%	61%
576	961
377	4,742
17%	51%
△4	∆31
373	4,711
44	1,160
329	3,551



(2) Profit Analysis



Key Profit Analysis

(unit: KRW 100Mn)



Operating Profit 2,539

- Increase in Novavax License-in DS revenue
- Realization of Novavax/AZ COVID-19 vaccine
 DS CMO manufacturing revenue

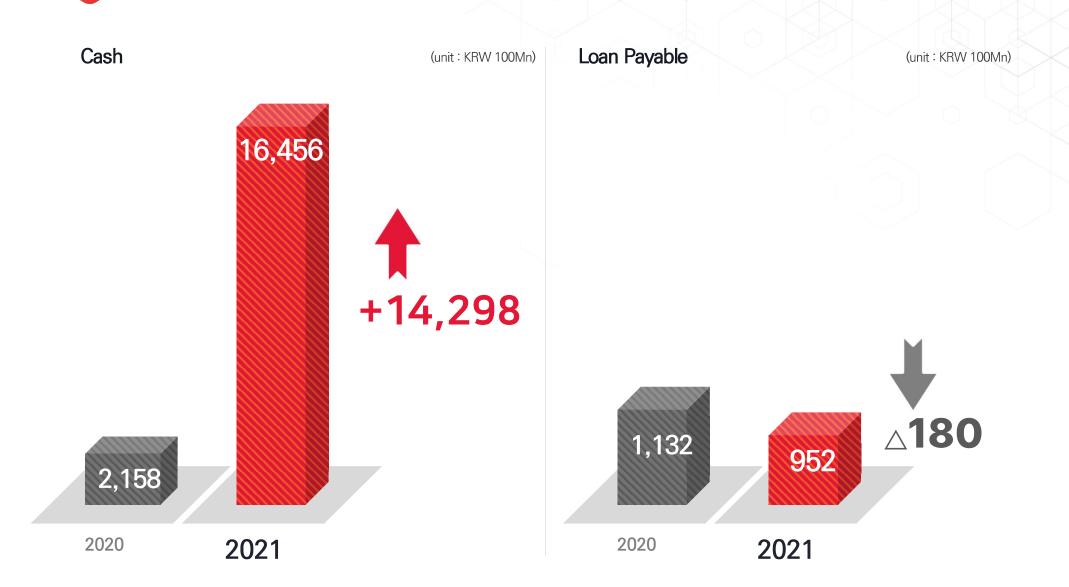
Net Income 1,840

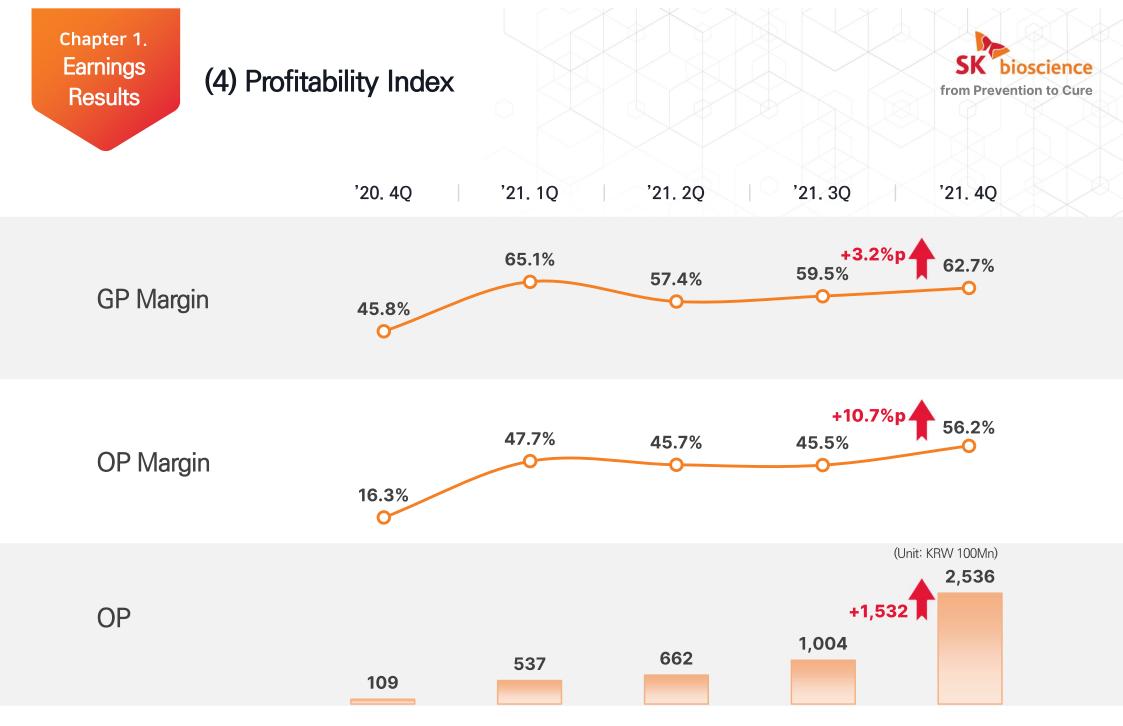
• Expenses, incl. income tax, △675 reflected



(3) Balance Sheet Highlight









(5) Financial Statement



Balance Sheet

(Unit: KRW Mn)

Cataman			
Category	2019.12.31	2020.12.31	2021.12.31
Total Assets	403,980	562,232	2,110,123
Current Assets	170,741	333,902	1,837,804
Cash & cash equivalents	94,468	215,898	1,645,663
Account receivable & other receivable	32,430	45,838	48,135
Inventories	36,378	70,275	135,046
Other current assets	7,465	1,891	8,960
Non-current Assets	233,239	228,330	272,319
PP&E	182,477	180,992	210,265
Intangible assets	19,479	17,858	17,061
Other non-current assets	31,283	29,480	44,993
Total Liabilities	171,246	298,442	508,811
Current Liabilities	45,509	180,640	459,952
Account payable & other payable	31,613	39,153	102,185
Short-term borrowings	-	-	11,671
Current bonds	-	10,995	47,978
Current contract liabilities	4,687	94,899	98,789
Other current liabilities	9,209	35,593	199,329
Non-current Liabilities	125,737	117,802	48,859
Bonds	93,472	80,473	35,503
Long-term borrowings	23,156	21,760	-
Other non-current liabilities	9,109	15,569	13,356
Total Equity	232,734	263,790	1,601,312
Capital stock	10,200	30,600	38,250
Capital surplus	201,219	180,518	1,157,064
Other equity	325	901	901
Accumulated other comprehensive income	△1,319	△1,465	△208
Retained earnings	22,309	53,236	405,305
Net Cash	△22,160	102,671	1,550,512

Income Statement

(Unit: KRW Mn)

Category	4Q.20	2020 Cum.	1Q.21	2Q.21	3Q.21	4Q.21	2021 Cum.
Revenue	67,009	225,611	112,710	144,604	220,829	450,858	929,001
COGS	36,293	130,269	39,308	61,566	89,476	168,368	358,718
Gross Profit	30,716	95,342	73,402	83,038	131,353	282,490	570,283
SG&A expenses	19,804	57,632	19,687	16,884	30,946	28,546	96,063
Operating Profit	10,912	37,710	53,715	66,155	100,406	253,944	474,220
Non- operating profit & loss	△283	△417	1,327	1,737	∆3,834	∆2,322	∆3,092
Profit before Income Tax	10,628	37,293	55,042	67,892	96,572	251,622	471,128
Income tax	750	4,404	13,117	15,080	20,135	67,656	115,989
Net Income	9,878	32,890	41,925	52,812	76,437	183,966	355,139



1

GBP510 Clinical Trials

2

COVID-19 Variant Vaccine Development

3

Development Plan for COVID19 + Flu Combo

4

New R&D Project: Pan-Sarbecovirus Vaccine 5

New Business Initiative Roadmap

6

Next-gen
Pneumococcal Vaccine

7

mRNA Platform Development & Acquisition

8

Expansion of Andong L-House

9

Songdo R&PD Center Project

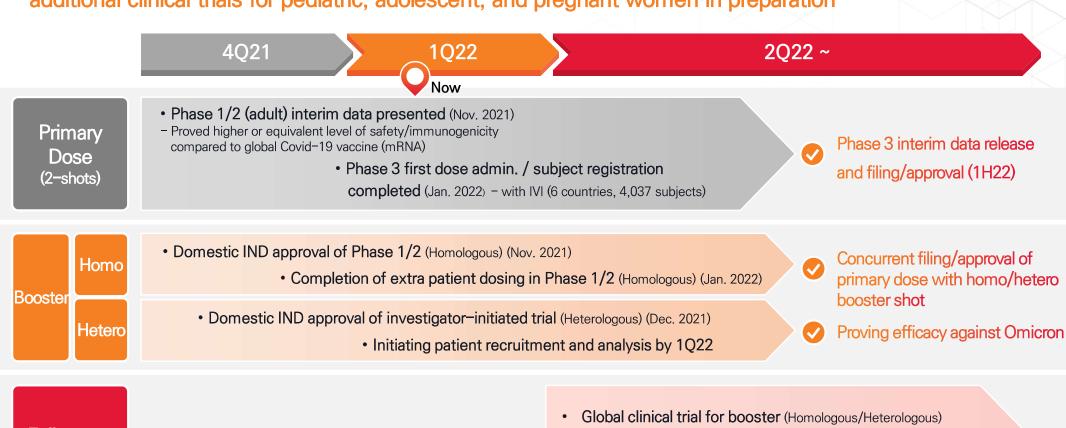




(1) GBP510 Clinical Trials



Global Phase III and booster clinical trials are in smooth progress given positive phase 1/2 results, with additional clinical trials for pediatric, adolescent, and pregnant women in preparation



Follow-up Clinical Trials

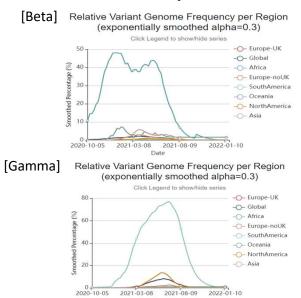
- Clinical trial for pediatric & adolescent (Domestic/Global)
- Clinical trial for pregnant women (Global)

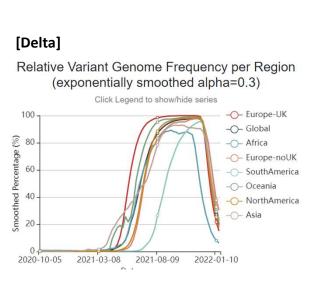
(2) COVID-19 Variant Vaccine - Spread of Omicron

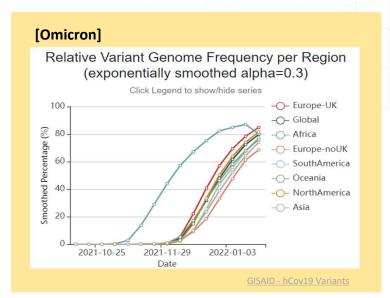


Continuous occurrence of variants has led to a drastic increase in COVID-19 cases since EOY 2021, yet Delta variant in recession with expedient spread of Omicron has resulted in decreased disease severity

Case count for key variants







WHO VOC (Variant of Concern)

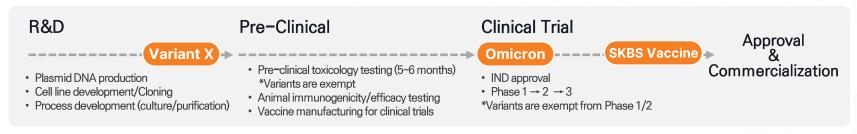
VOC	Outbreak Date	RBD Mutation(331~528 aa)
Beta (B.1.351)	10. 2020 (South Africa)	K417N, E484K, N501Y
Gamma (P.1)	12. 2020 (Brazil)	K417T, E484K, N501Y
Delta (B.1.617)	12. 2020 (India)	L452R, T478K
Omicron (B.1.1.529)	11. 2021 (South Africa)	15 variants G339D, S371L, S373P, S375F, K417N, N440K, G446S, S477N, T478K, E484A, Q493R, G496S, Q498R, N501Y, Y505H

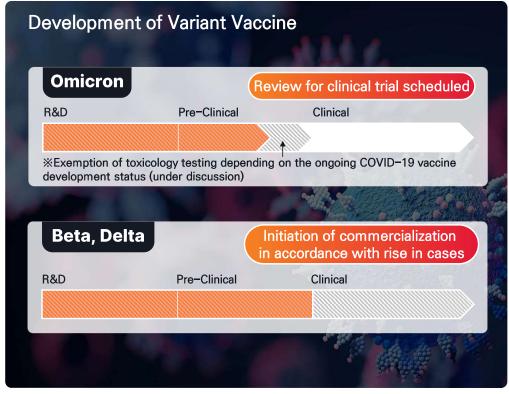


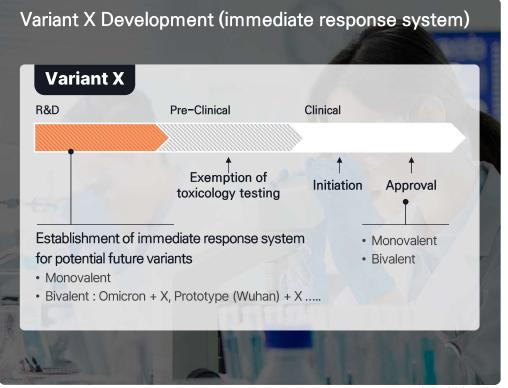
(2) COVID-19 Variant Vaccine - Omicron Variant



SK bioscience is developing additional vaccines against leading variants; clinical trials for Omicron vaccine set for review in close future and response system for future variants under development



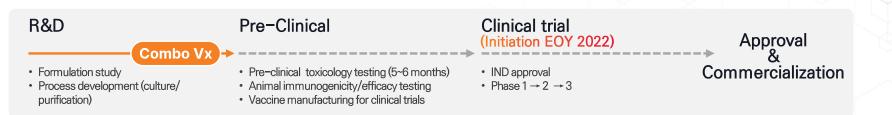




(3) Development Plan for COVID19 + Flu Combo

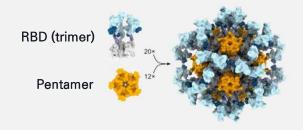


Development of combo vaccine is also underway with clinical trials scheduled for EOY 2022, combining COVID-19 vaccine with in-house developed flu vaccine, SKYCellflu, sold 40Mn+ doses globally



COVID-19 Vaccine

- Utilizing SKBS's in-house COVID-19 vaccine development technology
- Reviewing available variants as additional antigen candidates
 - Delta, Omicron. etc



Combo Vaccine



SKYCellflu

- Developed and marketed by SKBS globally (sold more than 40 Mn doses)
- Approved in South Korea, Thailand, Iran, Singapore, Malaysia, Philippine, Mongolia, Myanmar, and Brunei (additional approval in progress)



Initiation of Clinical Trial EOY 2022

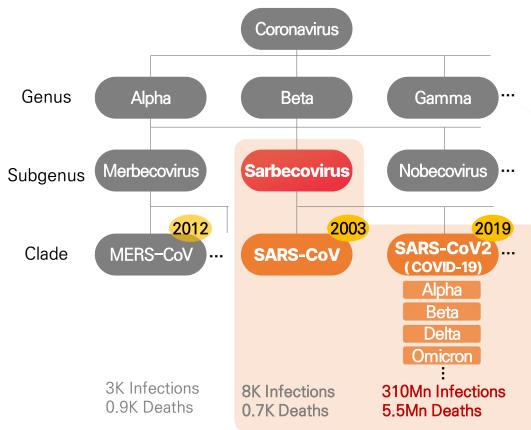
(4) Pan-Sarbecovirus Vaccine - Significance



Preemptive response is required against future pandemics/endemics, given the history of three coronavirus outbreaks since 2000 and the continuous mutation and rise of Sarbecovirus variants

Coronavirus Lineage

- The Sarbecovirus subgenus is the leading cause of pandemic
- The classification of coronavirus genera/subgenus/clade:



"A dream vaccine would cover not only SARS-CoV-2
... but also future variants of concern and other
coronaviruses... a more realistic and urgent goal is for
a pan-sarbecovirus vaccine" 1)

- Sarbecovirus is the most contagious and hazardous subgenus with the greatest level of inter-human infection
- "... all zoonotic sarbecoviruses identified to date use hACE2 as the entry receptor, which ensures a higher chance of success in generating a pan-sarbecovirus vaccine" 1)

"[Sarbecovirus] multivalent vaccines ··· [highlight] the potential to achieve broad sarbecovirus immunity overcoming both the emergence of SARS-CoV-2 variants and putative future zoonosis of genetically distinct sarbecoviruses" ²⁾

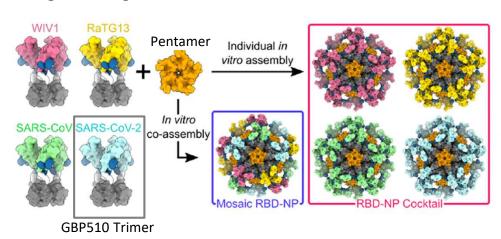
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(4) Pan-Sarbecovirus Vaccine – Development Status



We are currently propelling a new R&D project for a pan-Sarbecovirus vaccine, based on GBP510's nanoparticle platform and robust global collaboration

Antigen Design for Sarbecovirus Vaccine



Broadly protective vaccine antigen design against entire Sarbecovirus subgenus including COVID-19 variants and SARS virus

- RBD display of four Sarbecovirus clades
 SARS-CoV-2 (COVID-19), SARS-CoV (SARS), and Bat SARS-like WIV1 & RaTG13
- Utilizing the GBP510 nanoparticle (NP) platform
- Neutralization potency for RBD-NP against COVID-19 variants and other Sarbecovirus clades confirmed in early study¹⁾

R&D Partnership

Pre-clinical



- Antigen design and development
- Immunogenicity assay



- Animal testing
- Vaccine Assessment

Phase 1/2

Phase 3

BLA

Commercial Production



Toxicology testing & process development Vaccine manufacturing for clinical trials Phase 1/2 clinical trial operation Secured USD 50mn Funding from CEPI

i

Discussions scheduled for new & additional global partnership and funding opportunities



(e.g. CGT CDMO)

(5) New Business Initiative Roadmap

New Bio Area



Mid/Long-Term Portfolio	Strategic Direction and Goal	Execution Methodology and Current Status
	✔ Product Portfolio Expansion	 Acquisition of vaccine product/pipeline → Conducting strategic analysis of global/vaccine-oriented pharmas to leverage opportunities from their business restructuring/rationalization Long-listing of vaccine-specialized independent companies and consistent monitoring to screen for potential target
SYSS SYSS		 Investment in a local company and/or establishment of JV to secure early access and capability for overseas market entry → Implementation of the SKYShield business model
Reinforcing Existing Vaccine Business	Capability Enhancement	M&A of companies with foothold established in advanced markets and competitive global NRA approval/production capabilities
	Acquisition of New Platform Technology	 Prioritizing and screening for relevant/promising technologies in the market in line with SKBS's needs Pursuing technology licensing and equity investment parallelly
FRQ	✓ CGT CDMO	 Pursuing M&A, minority investment, and partnership parallelly Short-listing and network management of prioritized companies
New business	Additional Expansion into	Completed study of promising areas including biotherapeutics

Conducting review of companies with potential for platform technology

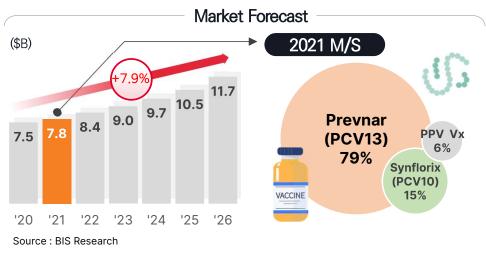
commercialization and synergy with SKBS's current business

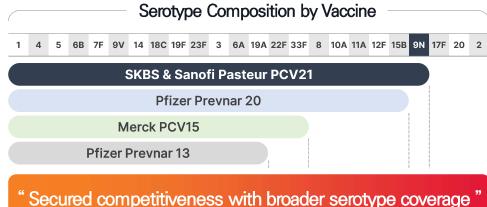
(6) Next-gen Pneumococcal Vaccine: PCV21



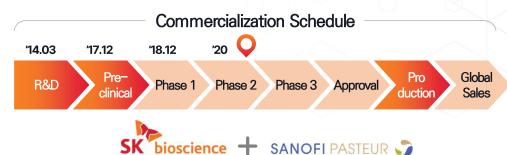
SKBS-Sanofi's next-generational PCV21 will raise the bar in the pneumococcal vaccine market, providing broader serotype coverage versus licensed pneumococcal conjugate vaccines in the market

Pneumococcal Vaccine Market





Development Status



SKBS-Sanofi partnership generates mutual complementation of R&D/clinical trial/manufacturing capabilities and risk sharing across future investments

Global Phase 2 Clinical Trials (All age-groups)



Read-out in all 3 populations expected by EOY 2022; Phase 3 initiation planned in 2023

(7) mRNA Platform Development & Acquisition



Mid/long-term collaboration is underway through 1) introduction of key mRNA technologies and 2) investment in companies with complete platform to secure comprehensive in-house capabilities

Strategy for mRNA Platform

- Securing key technologies by partnership (licensing)
- Expanding by next-gen technology development
- Prioritizing projects with global public health impact (e.g. vaccine for next pandemic) ex. COVID-19 variant/combo vaccine. Pandemic influenza vaccine

Short Term Strategy

Individual licensing of key technologies

- Technology components validated via marketed mRNA vaccines or those with potential for product-side improvement
- 1 Modified NTP

- 2 5'capping
- 3 LNP (Lipid Nanoparticle)
- 4 Other technologies

- Secured in-house capability for mRNA construct production and animal test data
- Licensing contract discussions ongoing with license owners of key individual technologies
 - Developing target products with both public and market needs

Mid/Long Term Strategy

Expanding application of mRNA tech. via collaboration with total platform companies

- Considering companies with:
 - 1) Ownership of comprehensive mRNA platform with proprietary rights on key technologies and know-hows
 - 2 Completed GMP process development
 - 3 Projects on infectious disease (including vaccines) and therapeutic applications

- Discussions ongoing with multiple (SI) and R&D collaboration model
- Various development projects expected to launch with partners, for expanded application of the mRNA platform



(8) Expansion of Andong L-House Manufacturing Plant



Andong L-House is transforming into a global vaccine/C(D)MO manufacturing hub through continued investment in facility expansion and upgrades, as well as acquisition of additional land plots

L-House Site Expansion





Capacity Expansion Plan

Current

DS Production

- 8 Cell culture suites
- 1 Cell bank

DP Production

- Pre-filled Syringe
- Liquid Vial
- Freeze-drying Vial
- Oral Injector



Phase 1 basic design in progress (completion by EOY 2024)

- GMP compliance
- FDA, EMA, WHO, MFDS
- DS production Facility
- Mammalian bioreactor 2.000L X 12EA +
- Microbial bioreactor 1,000L X 2EA + QC Center
- BSL2/BSL3 facilities

- DP Production Facility
 - Pre-filled Syringe
 - Liquid Vial
 - Freeze-drying Vial
- Warehouse



Phase 2 conceptual design and master-planning in progress, with target to triple current capacity

- DS Production Facility
- DP Production Facility

- OC Center
- Additional facilities

(9) Songdo R&PD Center Project



New R&PD center is in works to build a world-class vaccine hub/bio-ecosystem, with plans to boost 1 SKBS R&D infrastructure and 2 new business expansion via collaboration with global partners

R&PD (Research & Process Development) Center



R&D Lab	R&D facility expansion including BSL 2/3 LabR&D equipment upgrade
Pilot Plant	 Drug candidate manufacturing for clinical trials mRNA process development Cell and gene therapy (CGT) CDMO
Headquarter	Global-standard office environment
Open Lab	Co-R&D with partners, including international organizations/institutions
JV/Partner Space	Inclusive task-force space for maximum collaboration efficiency
Bio-Ecosystem	 Space for upstream/downstream collaborative opportunities (e.g. materials, components, equipment)
GMP Facility for Commercial Manufacturing	 GMP compliance: FDA, EMA, WHO, MFDS DS Production Facility Vaccine, CGT, mRNA manufacturing facility DP Production Facility PFS, Vials, Freeze Dryer QA/QC Facility Cold chain warehouse
	Pilot Plant Headquarter Open Lab JV/Partner Space Bio-Ecosystem GMP Facility for Commercial



Appendix

SKBS Pipeline at a glance



The SKBS pipeline includes various projects based on continuous R&D investment, with four promising blockbuster candidates for the global market

Blockbuster Pipeline	Pre-Clinical	Phase 1	Phase 2	Phase 3	Registration
CEPI BILL MELINDA GATES foundation				✓ Global	
2 Next-gen PCV21 SANOFI PASTEUR 🗳			✓ US		
3 COVID-19+Flu Combi	~				
4 Pan-Sarbecovirus CEPI Protein Design UNIVERSITY of WASHINGTON	✓				
NRRV PATH OCIAO+//2D0 BILL & MELINDA GATES foundation				✓ Africa	
TCV International Vaccine Institute BILL & MELINDA GATES foundation					BLA submitted for export
HPV Quadrivalent (NBP615)		✓ Ph	nase 1/2		
Rotavirus Pentavalent (NBP613)		~			
Hepatitis A Recombinant Zoster	~				
Cancer/Obesity Vaccine, etc.	~				
Others (mRNA, adjuvant)	~				

