IR Book | Aug. 2022

ST PHARM

Technology Driven Gene therapy CDMO From Oligonucleotide to xRNA



ST PHARM

During past three decades, ST PHARM has been recognized as a top-tier Oligonucleotide API manufacturer in the world.

We are committed to provide excellent services through continuous investments in R&D and quality, as well as effective communications and close partnerships with the clients.



> Introduction

- Dong-A Socio Group
- History / Facility
- Business Strategy
- Global Family (Affiliates)

Market

- xRNA Market
- Oligonucleotide
- mRNA

> Business

- Overview
- CDMO
- CRO
- R&D

> Financial Highlight

- Earnings figures
- Other Information
- Appendix



Introduction

MISSION (DONG-A SOCIO GROUP)

Infinite challenge for a human being with happiness & health **DONG-A SOCIO GROUP**

VISION 2030 (ST PHARM)

The Innovative Company Saving Life

- · 3 companies listed in Public
- · 5,000 people in the Group
- · 800 in ST PHARM

HEALTHCARE

ST PHARM

CDMO/CMO/CRO New Drug Development

Dong-A ST

Prescription Drugs New Drug Development

DM BIO

Biosimilar Dong-A & Meiji JVC

Dong-A **Pharmaceutical**

Over The counter Drugs

NON-HEALTHCARE

Dong-A **OTSUKA**

Food and Beverage Dong-A and Otsuka JVC

YONGMA LOGIS

Logistics & Storage

SOO SEOK

Bottles & Packaging

DA INFORMATION

IT Business & Solutions

Introduction HISTORY & SUPPLY RECORD

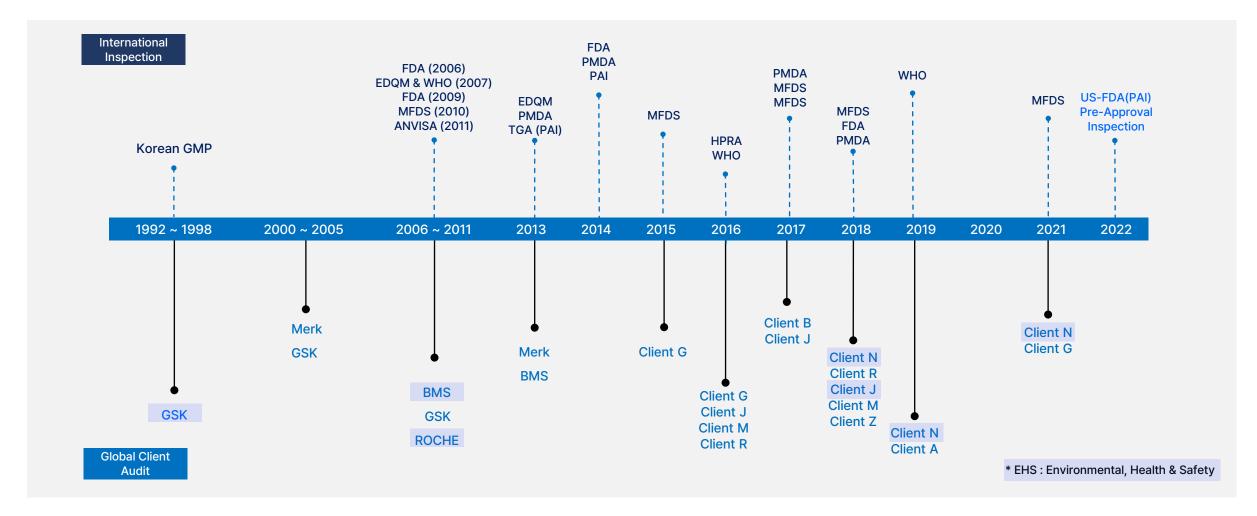
ST PHARM HISTORY

1983	Foundation of Samchully Pharm
2010	Joined Dong-A Socio Group and the corporate name changed to ST PHARM (Science and Technology)
2015	Completed 2 nd Campus (Banwol) FDA(USA) and PMDA (Japan) cGMP Inspection
2016	EU cGMP Inspection/ Established a subsidiary (STAR, <i>USA</i>) Listed (IPO) as a public company (KOSDAQ: 237690)
2018	Commence Oligo GMP Manufacturing at Oligo Banwol Plant (1.8mol) Awarded 2018 Global API Manufacturing (Oligonucleotide) Growth Excellence Leadership by Frost & Sullivan
2019	Acquired two CRO(AnaPath R&S) in Europe STP1002(Colorectal cancer) IND approval (<i>Phase1</i>)
2020	Received 2019 Roche CDMO Award STP0404 (AIDS) IMPD approval (<i>Phase1</i>)
2021	Established <i>LEVATIO</i> and <i>VERNAGEN (USA, RNA biotech)</i> Initiated Mid-scale mRNA GMP facility set up (<i>Banwol Campus</i>) Started development of COVID-19 vaccine (mRNA) <i>Disclosed Oligonucleotide 2nd plant plan (Banwol Campus)</i>
2022	STP2104 (COVID19, mRNA Vaccine) IND approval (<i>Phase1</i>) Awarded 2022 Global API Manufacturing(Oligonucleotide) Growth Excellence by Frost & Sullivan Completed 1st & 2nd Oligo plant expansion (6.4 Mole) STP0404 (AIDS, small molecule) Phase1 completed

SUPPLY RECORD 1988 Supplied Thymidine (dT) to GSK and BMS World-largest supplier of **Thymidine (dT)** 2000 Supplied API (Zidovudine, 1st HIV/AIDS drug) to GSK Largest global supplier of nucleosides by early 2000s 2002 Supplied API (Telbivudine, HBV drug) to Novartis 2004 2007 Supplied API (HCV drug) for clinical trials to Roche Supplied API (Atazanavir, HIV/AIDS drug) to BMS 2012 2013 Supplied API of first HCV cure drug for commercial use to Gilead 2015 Supplied Oligo API for clinical trials Supplied Oligo API for clinical trial phase III 2020 2021 Supplied *Oligo API* for commercial use

2022





Successfully Inspected by









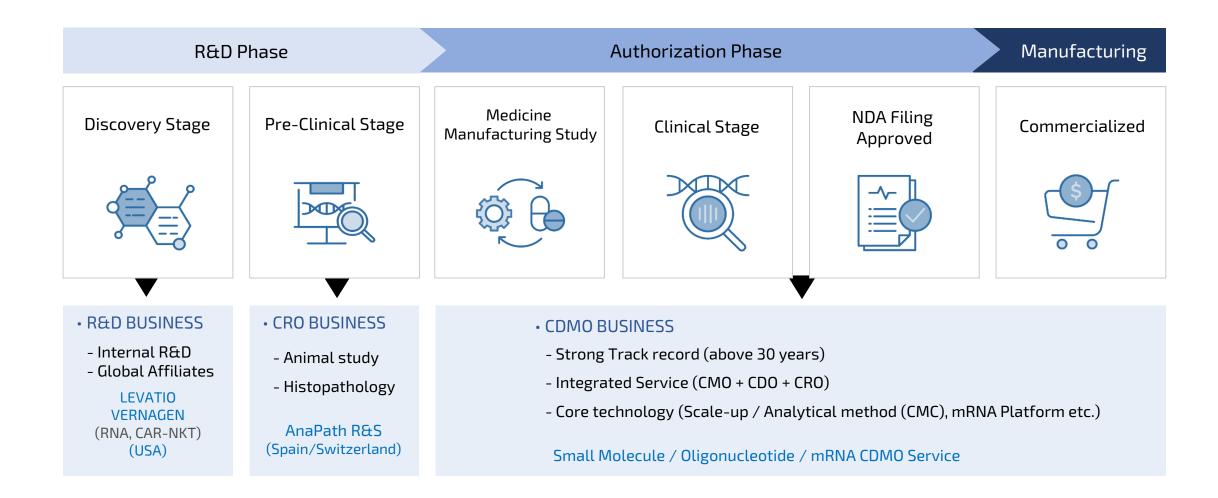








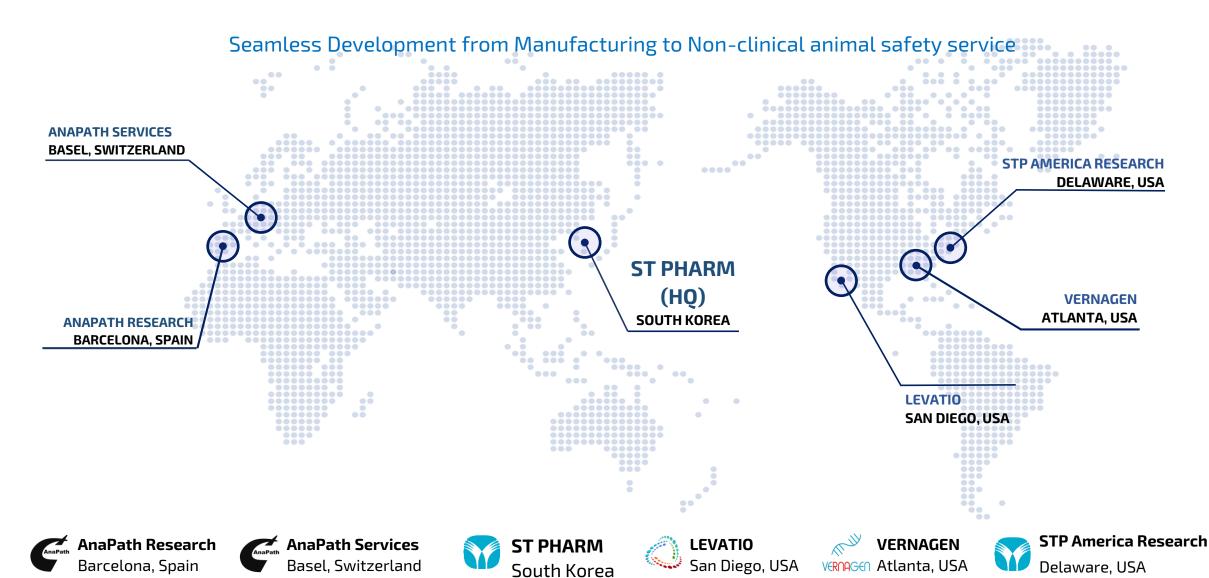
Introduction BUSINESS STRATEGY



ST PHARM is running CDMO, CRO and R&D and diversifying business portfolio in parallel



ST PHARM GLOBAL FAMILY





Market Overview





RNA-based Therapeutics' Concept

Overview

RNA-based therapeutics, fundamentally controlling gene expression (disease-relevant gene), 3rd generation therapy

* ST PHARM has manufactured API (Oligonucleotide) and provided CDMO services.

RNA based drugs

- Type: Anti-sense (ASO), siRNA, mRNA, Aptamer, miRNA etc.
- Approved drugs (e.g.): 1. Spinraza (Biogen) (SMA) * Sales USD 2.1Billion/year

2. Leqvio (Novartis) Cardiovascular disease

Advantages & Challenges

- Advantages

Rapid and cost effective development (Under 2 years)

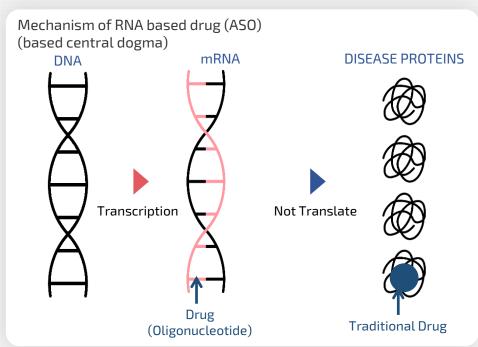
Targeting undruggable pathways

Long term effect (Leqvio 2T/annum VS Repatha 1-2T/monthly)

Price (Leqvio below \$4000/annum VS Repatha about \$5850/annum)

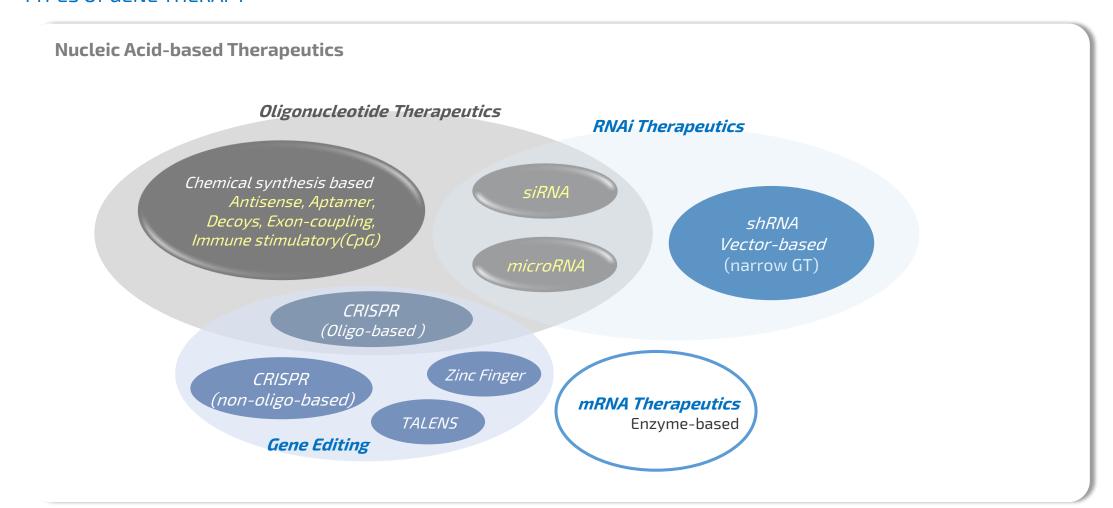
- Challenges

Delivery issues (to penetrate specific cell) cf. Liver, Spinal cord, etc Mass production (Few CDMO in global market)



RNA-based Therapeutics' Concept

TYPES Of GENE THERAPY







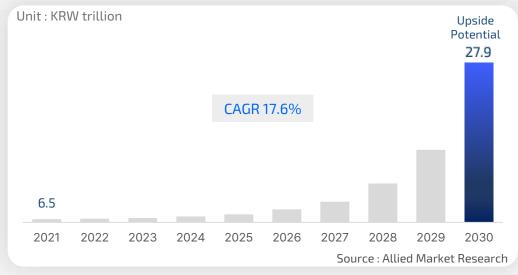
RNA-based Therapeutics' Market

New paradigm of therapeutics

Recent advances in cellular delivery of RNA drug have enabled development of RNA-based drugs for a broad array of applications, ranging from cancer to pandemic influenza.

• RNA therapeutics' market

- Global RNA based drug market size :
 - * 6 KRW trillion (2021) 28 KRW trillion (2030)
- Delivery technology (ex. Gal-Nac) Chronic disease drugs
- Global RNA based drug market (Except for mRNA vaccines)



Global Pipelines

Туре	Name	Indication	Company	Approved Year
siRNA	Leqvio	PCSK9 Inhibition (hyperlipidemia)	Novartis	2020
mRNA	Spikevax	COVID-19 Vaccine	Moderna	2020
mRNA	Comirnaty	COVID-19 Vaccine	Pfizer & BioNtec	2020
siRNA	Oxlumo	Hyperoxaluria type 1 (PH1)	Alnylam	2020
ASO	Vyondys 53	Duchenne muscular dystrophy	Sarepta	2019
siRNA	Givlaari	Acute hepatic porphyrias	Alnylam	2019
ASO	Tegsedi	Hereditary ATTR	Ionis	2018
siRNA	Onpattro	Hereditary ATTR	Alnylam	2018
ASO	Spinraza	Spinal muscular atrophy (SMA)	Ionis	2016
ASO	Exondys51	Duchenne muscular dystrophy	Sarepta	2016

Source : Research & Market

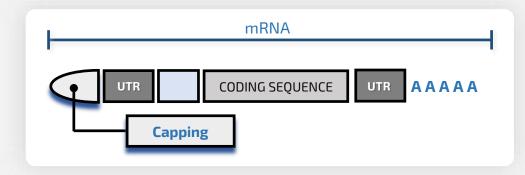




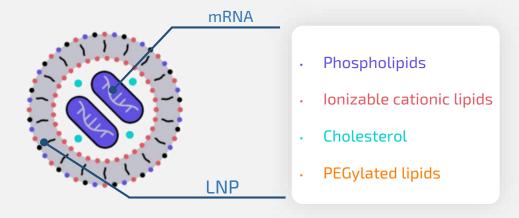
RNA-based Therapeutics (mRNA Concept)

mRNA Platform (Core technology)

1) 5' Capping (Synthesis technology)

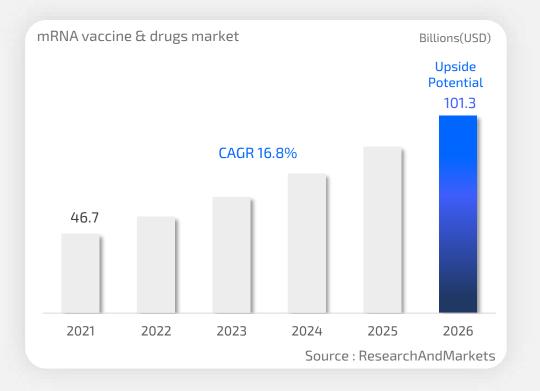


2) LNP (Lipid Nanoparticle) – Delivery vehicle



• mRNA vaccines & therapeutics market

- The opportunity for rapid development and manufacturing against emerging pathogens, as demonstrated with Covid19 vaccines.
- Rapid drug development (Avg. 10 years > 10 months)
- Increased trend in L/O events





RNA-based Therapeutics (mRNA Concept)

mRNA manufacturing process

DRUG SUBSTANCE



IVT Synthesis

- pDNA linearization
- In-house codon optimization
- Ample experience in IVT optimization
- Strategic Partners

ST PHARM



New 5' Cap Analog

- Novel cap analog (SmartCap®) to stabilize mRNA
- Screening capping library to select the best capping analog

Formulation (DDS)

- LNP To protect the encapsulated mRNA from degradation after injection into human body
- From In-licensed LNP to 3rd generation LNP developed by the diverse partners in the field

DRUG PRODUCT



Fill & Finish

- Final step
- A sterile filtration and filling of the vaccine into vials

STPHARM connects all aspects of mRNA drug development to clinical and commercialized production



RNA-based Therapeutics (mRNA)

Overview

2020 was a breakout year for mRNA technology platforms with the launch and widespread use of mRNA vaccines for COVID 19.

The global market for mRNA therapeutics grows from \$46.7 billion in 2021 to \$101.3 billion by 2026 (CAGR 16.8%)

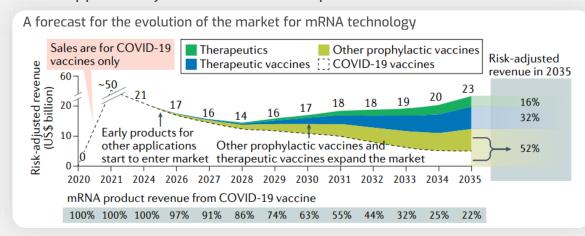
- mRNA therapeutics
 - Safety/ Specificity (binding to target disease)

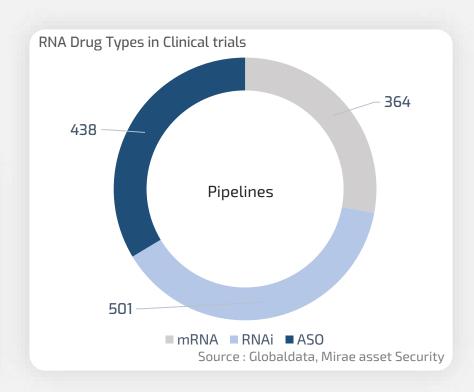
No risk of genomic integration /

Inducing protein coding and inhibiting translation

- Capacity for rapid development and potential for low-cost manufacture
- Essential roles in protein expression

Broad applicability in the treatment or prevention of disease







Business Overview



CDMO Business Overview

ST PHARM CDMO Strategy



1983. Nucleoside/tide

- Monomer (PNS / PA)
- Zidovudine (AIDS)
- Sofosbuvir (HCV)



2008. Oligonucleotide

- Antisense (ASO)
- siRNA / miRNA
- Aptamer
- Decoys
- Others



2018. Polynucleotide

- mRNA
- circRNA
- samRNA



CDMO (Oligonucleotide)

ST PHARM's Core Strength (Oligonucleotide CDMO)

- Global top-3 positioned service
- The only integrated In-House production capability in the global market (From monomer to oligonucleotide)
- Innovative manufacturing system (ex. Biotransformation technology)
- Strong track record in new drug API manufacture proven in US & Europe
 (+15 years)

Manufacturing Capacity Expansion (disclosed)

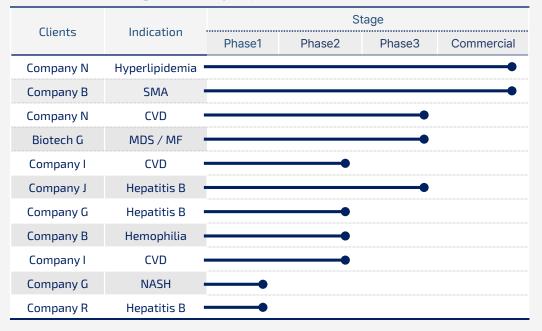
- 1st & 2nd expansion: Completed in 2022 2Q
 Installing additional manufacturing trains in Banwol plant
 (Initiate by Apr & June of 2022) * financial support from a global client (2nd)
- 3rd expansion: Additional building (Banwol campus) planned

Strong Track Record

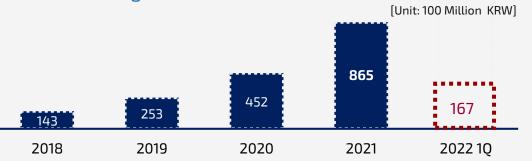
- -Awarded 2018 Global API Manufacturing Growth Excellence Leadership Award (Frost & Sullivan)
- -Awarded 2022 Asia-Pacific Oligonucleotide CDMO Company (Frost & Sullivan)
- -Roche CDMO Award 2019

Oligo New Drug (First in global), Small Molecule New Drug (First in Asia)

ST PHARM's Oligo CDMO projects



ST PHARM's Oligo CDMO sales



Capacity (Oligonucleotide)

ST PHARM plans to invest in total \$126 million USD to build a 2nd oligonucleotide manufacturing plant.

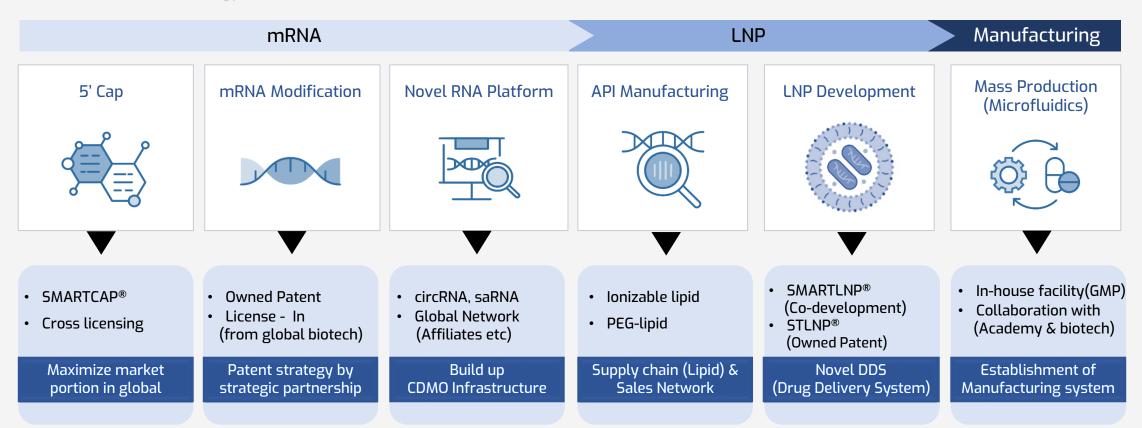
Oligo production	Current	2022, 3Q	2024, 3Q	2026, 1Q
ougo production	1 st Plant	1 st Plant (1 st & 2 nd expansion)	2 nd Plant (1 st stage)	2 nd Plant (2 nd stage)
Total CAPA (Facility / Line)	2.0 mole (about 500kg)	6.4 mole (1t-3.2t)	10.2 mole (1.7t-5.1t)	14.0 mole (2.3t-7t)
	1	4	7	10
	1.0 time	3.2 times	5.1 times	7.0 times





CDMO (mRNA)

mRNA Business Strategy



Establishment of mRNA CDMO Infrastructure by Technology Internalization (DDS) & Raw material production (Lipid)

Business CDMO (mRNA)

Core Technology

The only company have

1) 5'capping 2) LNP Platform Technology

ST PHARM's own patented Capping technology (SMARTCAP®)
ST PHARM's own patented LNP (STLNP™, SMARTLNP™)





- Stabilizing synthetic technology of mRNA
- Patented in Korea / USA (on going)
- Diverse cap analogues (over 30 types)
- Cost effectiveness

> CAP Library Screening System

- Customized cap analogues
 - customized client service
- Higher gene expression
 - flexibly able to control target gene



CDMO (mRNA)

Core Technology

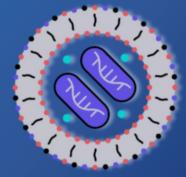
The only company have

1) 5'capping 2) LNP Platform Technology

ST PHARM's own patented Capping technology (SMARTCAP®)
ST PHARM's own patented LNP (STLNP™, SMARTLNP™)



- 1. In-Licensing LNP
- Proven, unsurpassed technology (applied to Covid19 vaccine)
- 2. ST Pharm LNP (STLNPTM)
- ST PHARM's own patented LNP ('2020)
- Platform for mRNA CDMO
- 3. Next generation LNP (SMARTLNPTM)
- Collaborations with E-HWA Women's Univ. in KOREA
- Improving stability and immune response

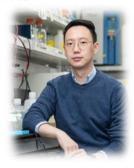


- STLNP™ /SMARTLNP™

LNP study (collaborations with academies)

Collaboration with Prof. Hyuk-jin Lee ('21.03)

- Prof. of Graduate school of Pharmaceutical
 Sciences at Ewha Womans University
- Focused on DNA nanotechnology for drug delivery and molecular diagnostics.
- Development of mRNA-LNP vaccine with ST PHARM (2021.03)





CDMO (mRNA)



> 1. R&D / Small scale production

mRNA plant ,1F (Banwol)

Completion: 2020.08

Capacity: gram / month (for pre-clinical)

2. Mid-scale production (GMP)

mRNA plant ,1F (Banwol)

Completion: 2021.05

Capacity: mg to multi-gram /month

3. Large / Commercial scale production (GMP)

mRNA plant, 3/5F (Banwol)

Capacity: 100-120g/month

* Customized facility available as per client's request



CRO

In 2019, Acquired Global CRO company in Europe (Client-dependent CMO ⇒ Client-leading CDMO)
After completion of restructuring in 2020, achieved of turnaround.

- AnaPath Research (Barcelona, Spain)
- Established in 1986 (Envigo, Spain)
- AnaPath acquired in Nov. 2019
- Building, 10 thousands sqm, Land, 20 thousands sqm
- More than 800 animals (e.g. monkey, rabbit, dog)



Project Mgmt



Sub-Contract

- AnaPath Service (Basel, Switzerland)
 - CSO: Klause Weber (Specialized in histopathology)
 - The biggest non-clinical CRO in Europe
 - GLP Approval (In 2006), Joined EU Safety Alliance
 - Up to 1000 experiments (chronic toxicity, carcinogen)

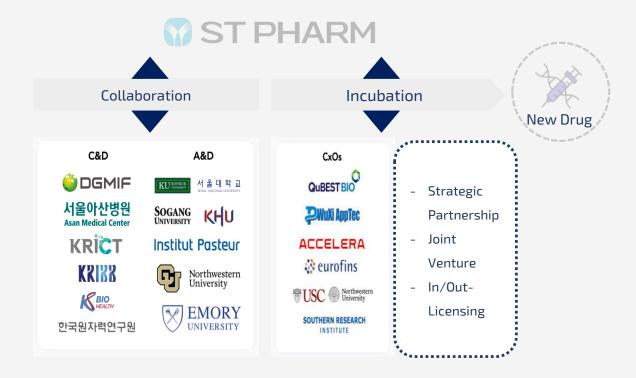




R&D (Virtual)

ST PHARM Virtual R&D

"Minimizing R&D cost and expediting drug development process" "Creating a synergy effect with API CDMO business"



ST PHARM Pipelines

"Anti-AIDS drug (First in class) in the world"

Long-term lasting injection type

"Anti-Cancer drug (First in class) in the world"

Curing patients with Kras/Nras mutation and drug resistance (Erbitux)

Pipeline	Double	Stage			
(Indication)			Pre-clinical	Phase1	
STP0404 (Anti-AIDS)	Emory Univ. Colorado State Univ.			•	
STP1002 (Anti-Cancer) (Solid Tumor)	Asan Hospital				
STP2104 (Covid19 vaccine)	In-house			•	
NASH	KRICT		•		
Oral Heparin	B&L Deli Pharm				
Anti-virus	KRICT				
Others (2)	Undisclosed		•		



R&D (Global Affiliates)

- LEVATIO Therapeutics (San-Diego, USA)
 - Establishment in San Diego (USA) for mRNA & CAR-NKT therapy
 - Based on novel circular RNA platform technology

(With ST PHARM's novel mRNA platform technology)

- Entry into the field of gene, cell therapeutics

Proof-of-Concept (POC)

 Development of first-in-class mR NA cancer vaccine and customize d neo-antigen vaccine

First-in-Class mRNA Therapy

· 'Off-the-Shelf' CAR-NKT cells engineered with mRNA



Strong data-driven POC modality validating potential of proprietar y mRNA technology and therape utic application



Technology

- circRNA + CAR-NKT (* Levatio)
- Cell / Gene therapeutics made by mRNA & circRNA & NKT cell
- circRNA: Excellent stability, Half-period(x2.5) compared to mRNA
- NKT cell : Cells with all the characteristics of T cells and NK cells $(\mbox{the 4^{th} Lymphocyte})$
 - * Suitable for mass production (Off-the-shelf)
 - * Activating immune system (Adjuvant)

Collaborations

- Open innovation strategy w/ academy, hospital, and research institute
- Synergistic collaborations
 w/STPHARM



Expansion of pipeline

- mRNA platform technology for developing cancer vaccines and 'Off-the-Shelf' CAR-NKT cells
- Cancer and autoimmune disease



Goal



Anti-Cancer

Autoimmune Disease



R&D (Global Affiliates)

VERNAGEN (Atlanta, USA)

A biotech startup that develop mRNA based therapeutics for unmet needs (infectious & genetic disease)

Purpose

- mRNA based therapy and vaccine (RSV vaccine etc.)
- Alternative drugs (Niche market penetration)
- Strategic partnership in global network

Strategic Plan

MAIN PIPELINES

"Phase 1 & 2 in 2024"

Pipeline	Stage			
ripetine	Discovery	Pre-clinical	Phase1	
RSV mRNA Vaccine				
Norovirus mRNA Vaccine	•			
SFTS mRNA Vaccine	-			
Hendra/Nipah mRNA Vaccine	•			
mRNA Therapeutic (Others)		•		

LAUNCH (2022 – 2023)

- Set up company
- Develop mRNA vaccines
- Complete Series A funding round

GROWTH (2024 – 2025)

- Establish partnership globally
- Secure mRNA technology
- Diversify profit model(L/O, Data driven collabo.)
- Complete Series B funding round

LEAP UP (2026 – 2028)

- Crate VERNAGEN (Brand Identity)
 - Global IPO (In 2028)
- Complete Series C funding round



Financial Overview





Earnings Summary

Achieved record high results in 2022. 1Q: Sales up 35.7%, +97 BN KRW (YoY) driven by Oligo business & CRO

[Linit · Million KDM]

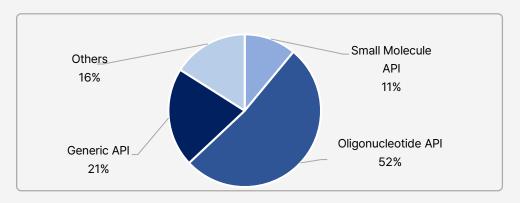
P/L (Consolidated)

				[Unit: Mi	illion KRWJ
	2022 1Q	2021 1Q	2021	2020	2019
Sales	36,978	27,257	165,642	124,109	93,257
COGS	20,397	22,935	107,899	104,123	94,885
Gross Profit	16,581	4,321	57,743	19,985	-1,628
SG&A	16,044	10,829	52,165	38,802	25,075
Operating Profit	536	(6,507)	5,578	-18,817	-26,703
Net Income	2,144	(5,056)	3,377	-13,154	-18,529
OCI	(1,495)	(295)	1,765	504	-328
CI	649	(5,351)	5,142	-12,650	-18,856

Sales breakdown

[Unit: 100 Million KRW]

Business	2022 1Q	2021 1Q	2021	2020	2019	YoY
Small Molecule API	19	28	179	154	118	16.23%
Oligonucleotide API	168	85	865	452	252	91.37%
Generic API	59	90	356	477	457	- 25.37%
Others	123	68	267	157	105	70.1%
Total	369	272	1,656	1,242	933	33.3%



Financial ()



Others

B/S (Consolidated)

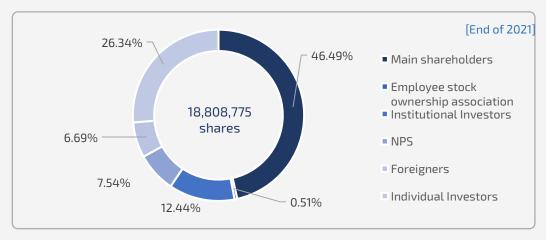
[Unit: Million KRW]

	2021	2020
Current Asset	244,142	235,613
Non-Current Asset	254,423	209,957
Total Asset	498,565	445,570
Current Liability	75,365	18,610
Non-Current Liability	97,167	130,206
Total Liability	172,532	148,817
Parent's Owners Equity	322,974	295,328
Capital stock	9,404	9,328
Paid-in capital stock	186,905	171,287
Capital adj.	11,074	3,079
Retaining Earnings	115,589	111,634
Minority Equity	3,058	1,425
Total Equity	326,033	296,753

Shareholders Status

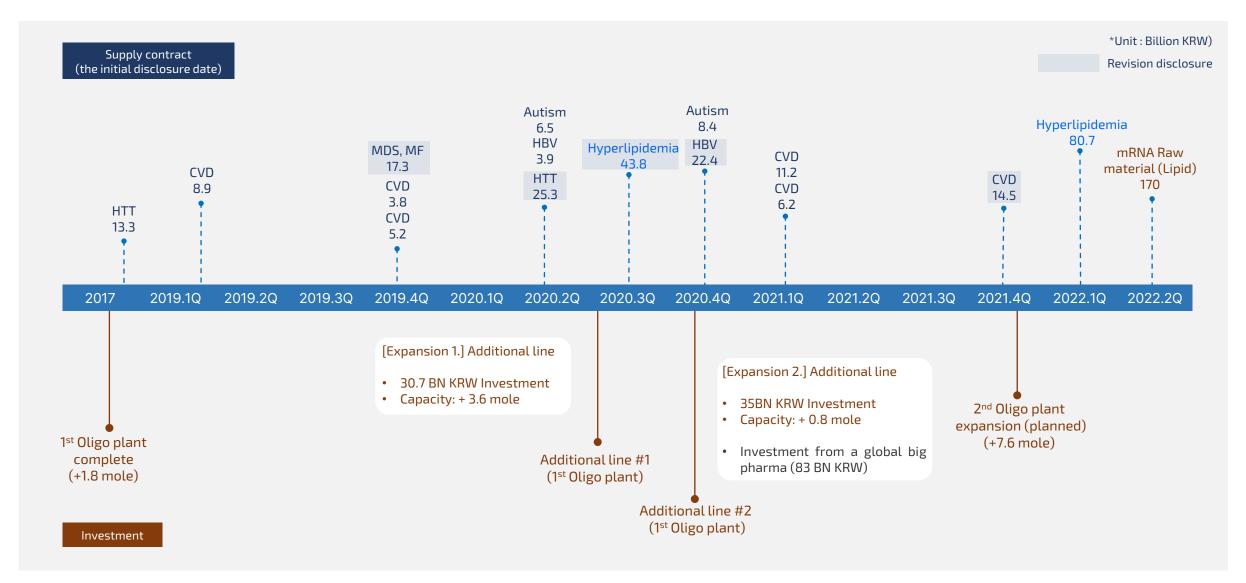
[Unit: Shares, %]

Name of Holders	Shares	Ratio	Note
Dong-A Socio Holdings	6,096,552	32.41%	Majority holder
Jung-Seok Kang	2,475,657	13.16%	Major holder of Holdings
Soo-suk culture foundation	171,600	0.91%	Foundation
NPS (National Pension Services)	1,417,609	7.54%	
Kyung-Jin Kim & 3 holders	9,507	0.05%	Board members
Others	8,637,850	45.92%	
Total	18,808,775	100.00%	





Appendix Disclosure Contents (Summary)



Thank You ST PHARM

Technology-Driven Gene therapy CDMO From Oligonucleotide to xRNA

