

IR Book | Apr. 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.



> Company

- Dong-A Socio Group
- Business Strategy
- Global Family
- History

> Market

- Oligonucleotide
- mRNA

> Business

- Overview
- CDMO
- CRO
- R&D

> Financial Highlight

- Earnings figures
- Other Information



PART 01

Company Overview



DONG-A SOCIO GROUP

- 3 companies ● listed in Public
- 5,000 people in the Group
- 678 in ST PHARM

HEALTHCARE

NON-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

Dong-A OTSUKA

Food and Beverage
Dong-A and Otsuka JVC

YONGMA LOGIS

Logistics & Storage

SOO SEOK

Bottles & Packaging

DA INFORMATION

IT Business & Solutions



MISSION

Infinite challenge for a human being with happiness & health

VISION 2025

Global Total Chemistry Company,
Providing with the world-best quality & service

CORE VALUES

VISION 2030 (ST PHARM)

The Innovative Company Saving Life



INNOVATION

Start from small innovations
from a new perspective



TRANSITION

Drive change
by
reading the trend



TRUST

Build trust generate
greater synergy



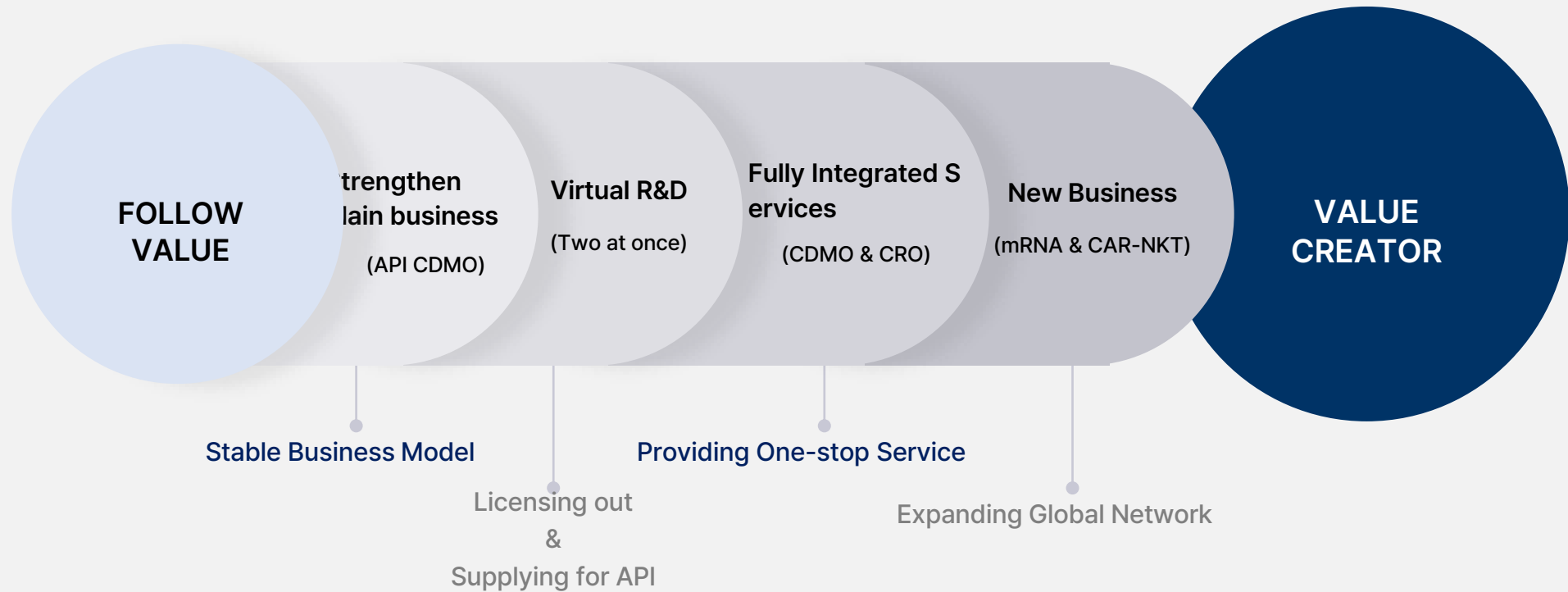
THRIVE TOGETHER

Grow with employees,
customers and society



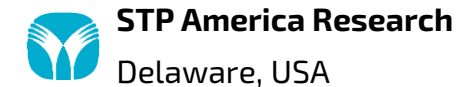
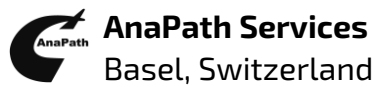
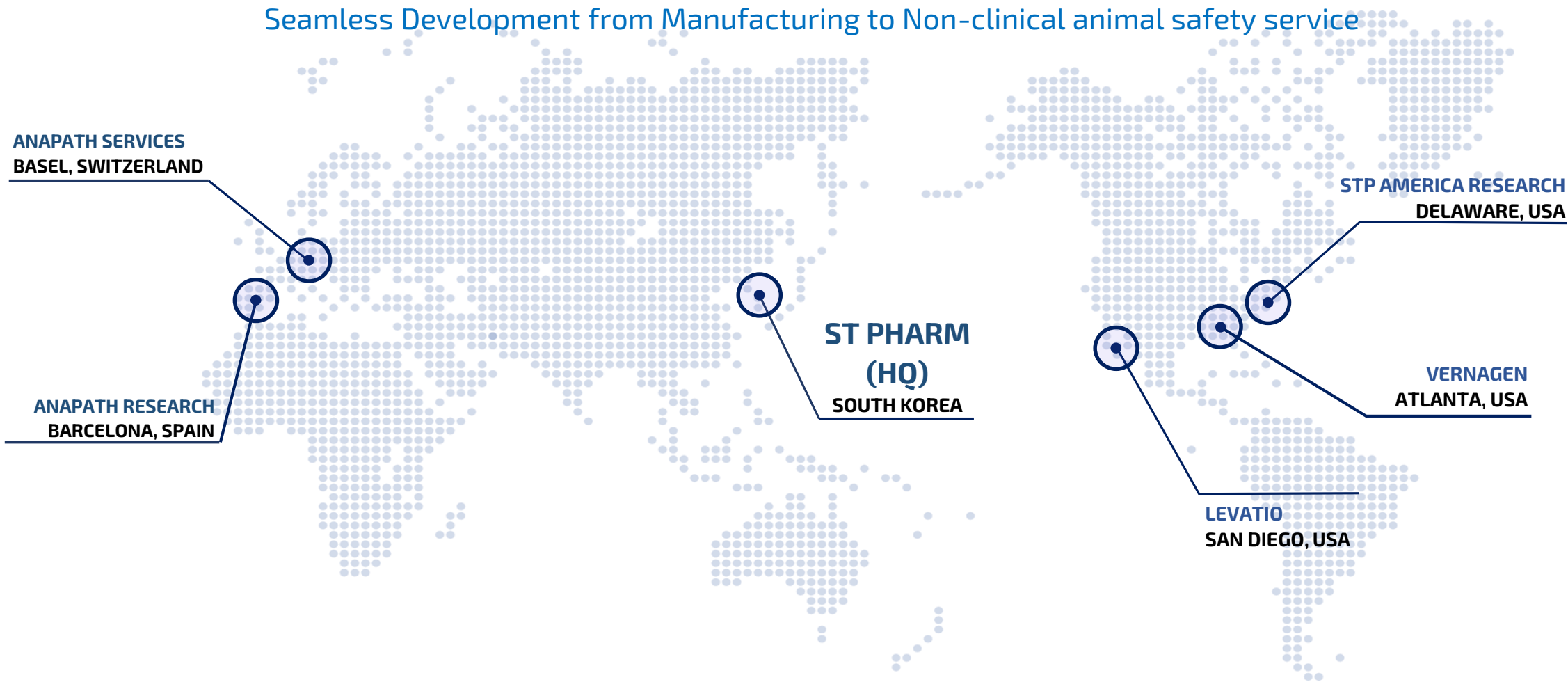
GREEN MANAGEMENT

Manufacture eco-friendly
for our better environment





Seamless Development from Manufacturing to Non-clinical animal safety service

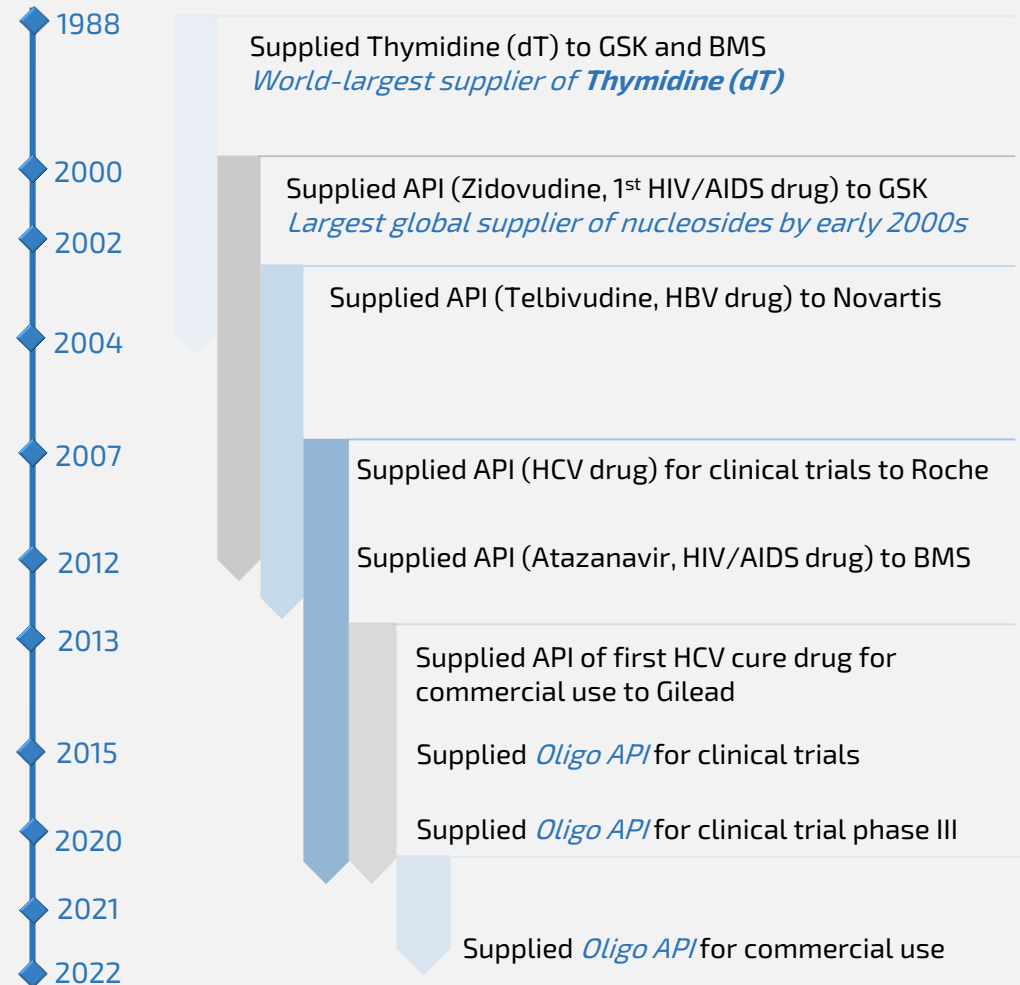




ST PHARM HISTORY

- 1983 Established as Samchully Pharm
- 1990 Strategic expansion of manufacturing facility and establishment of the R&D Center (Sihwa)
- 2010 Joined Dong-A Socio Group and the corporate name changed to ST PHARM (Science and Technology)
- 2015 Completed 2nd Campus (Banwol)
FDA(USA) and PMDA (Japan) cGMP Inspection
- 2016 EU cGMP Inspection/ Established a subsidiary (STAR, USA)
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 in Europe
STP1002(Colorectal cancer) IND approval (*Phase1*)
Received 2019 Roche CDMO Award
- 2020 STP0404 (AIDS) IMPD approval (*Phase1*)
Initiated Oligonucleotide Banwol plant capacity expansion (4.6mol)
- 2021 Established LEVATIO and VERNAGEN
Initiated Mid-scale mRNA GMP facility set up (Banwol Campus)
Started development of Covid-19 vaccine (mRNA)
Disclosed Oligonucleotide 2nd plant plan (Banwol Campus)

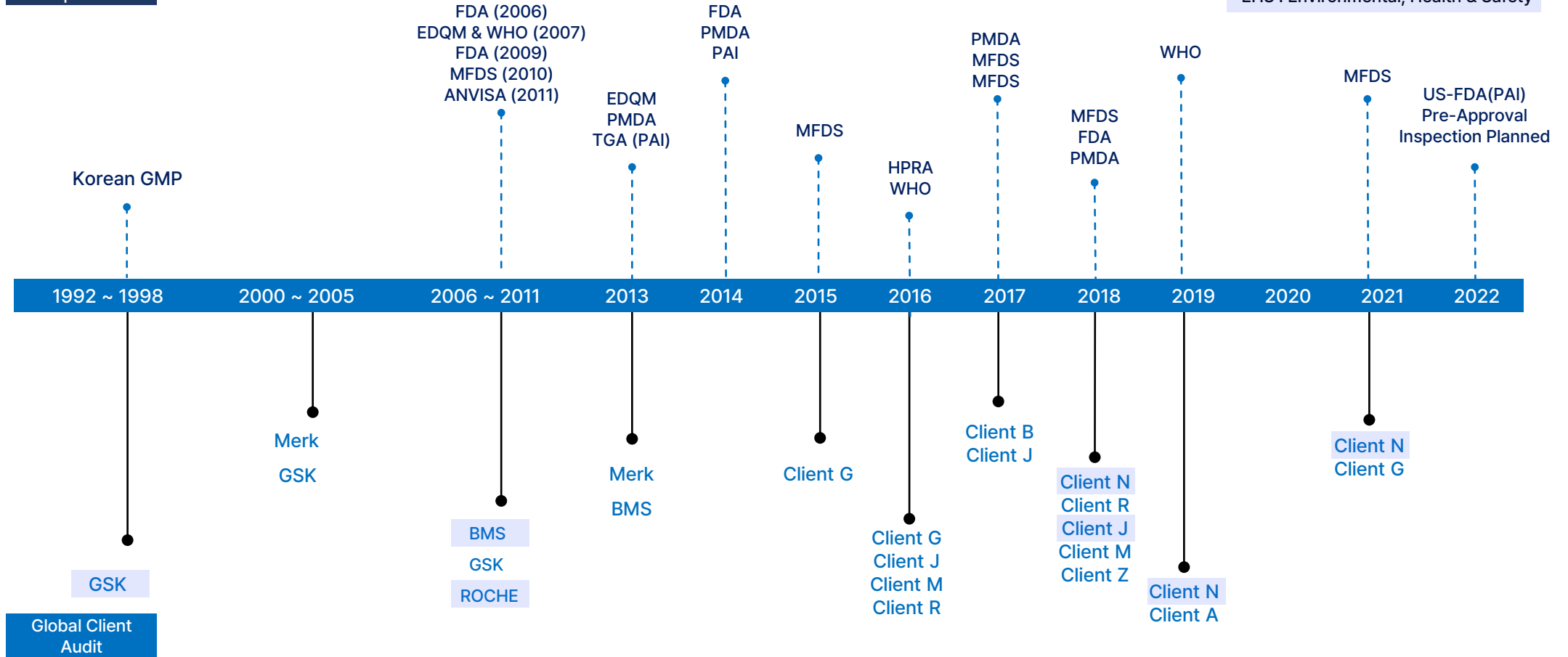
SUPPLY RECORD





International Inspection

* EHS : Environmental, Health & Safety



Global Client Audit

Successfully Inspected by





PART 02

Market Overview



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, cirRNA etc.**

- Approved drugs : 1. Spinraza (Biogen) (SMA) * Sales USD 2.1Billion/year

2. Inclisiran (Novartis) (CVD)

Advantages & Challenges

- Advantages

Rapid and cost effective development (**simpler and faster to manufacture**)

Targeting undruggable pathways

Long term effect (**Inclisiran 2 times/annum VS Repatha 1-2time/monthly**)

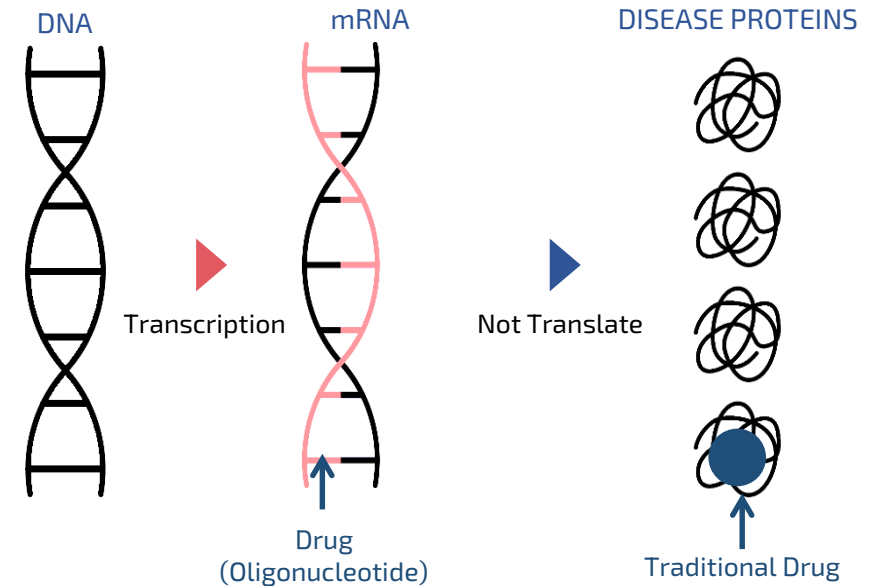
Price (**Inclisiran below \$4000/annum VS Repatha about \$5850/annum**)

- Challenges

Delivery issues (difficulty to penetrate cell) **cf. Liver, spinal cord, etc**

Mass production (few **CDMO** in global market)

Mechanism of RNA based drug





- **New paradigm of therapeutics**

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

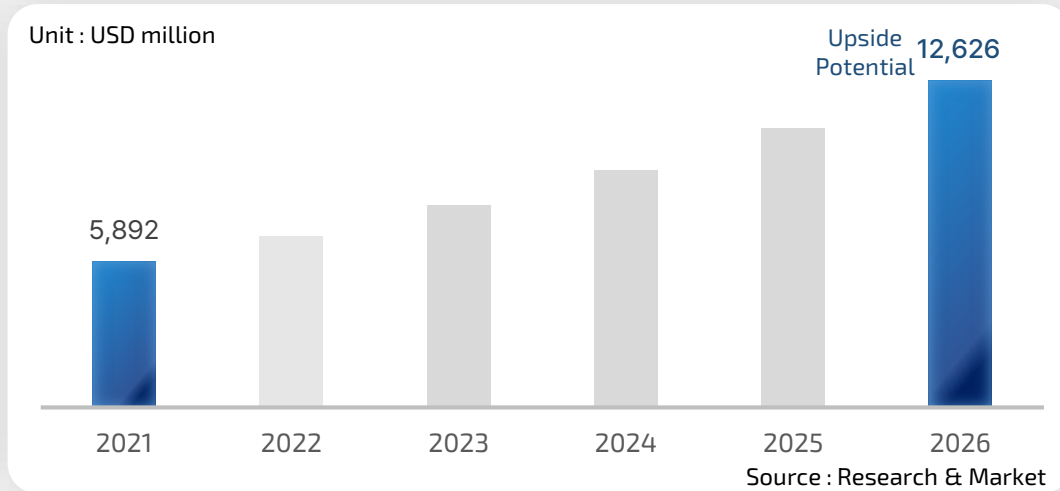
- **RNA therapeutics' market**

Global RNA based drug market size :

* **USD 5 Billion (2021)** ▶ **USD 13 Billion (2026)**

- Advances in the delivery of RNA drug (ex. Gal-Nac)

- **Global RNA based drug market**



- **Global Pipelines**

Type	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



Overview

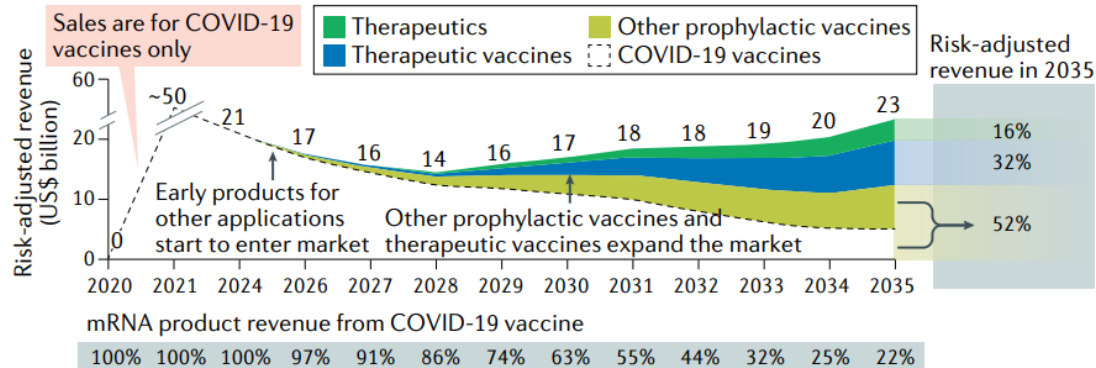
2020 was a breakout year for mRNA technology platforms with the launch and widespread use of mRNA vaccines for COVID 19.

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

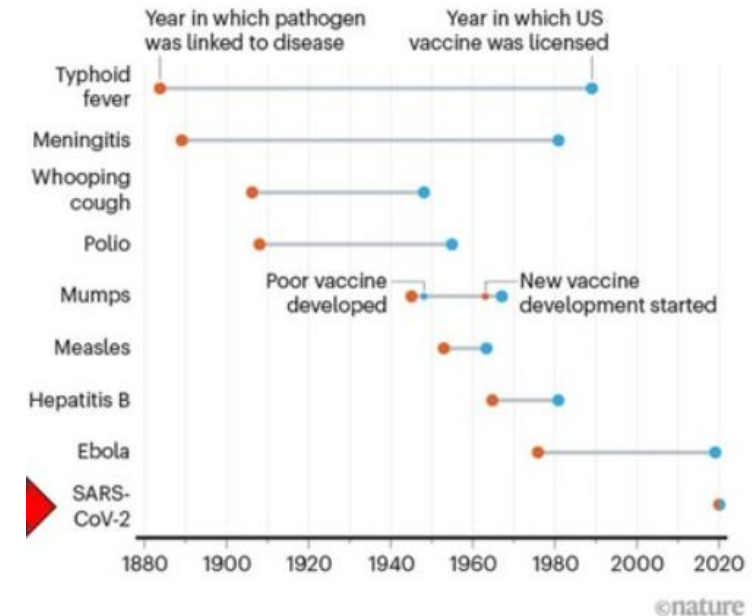
mRNA therapeutics

- Safety/ Specificity (to bind to target disease)
 - ▶ Without risk of genomic integration/ inducing protein coding, inhibiting translation
- Capacity for rapid development and potential for low-cost manufacture
- Central role in protein expression
 - ▶ Broad applicability in the treatment or prevention of disease

A forecast for the evolution of the market for mRNA technology



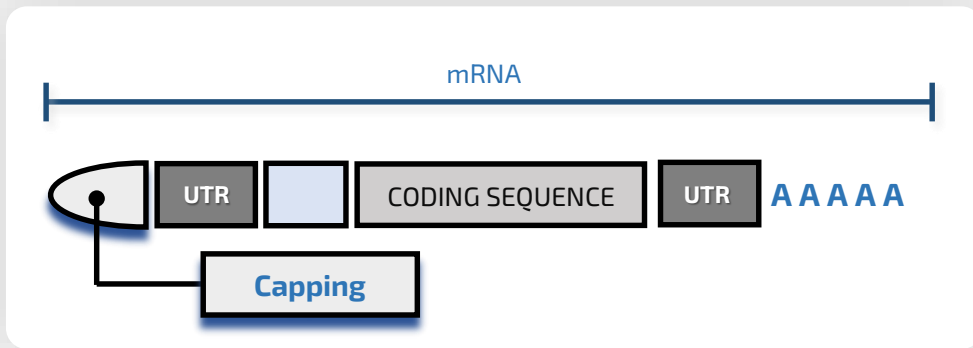
Development period of mRNA vaccine



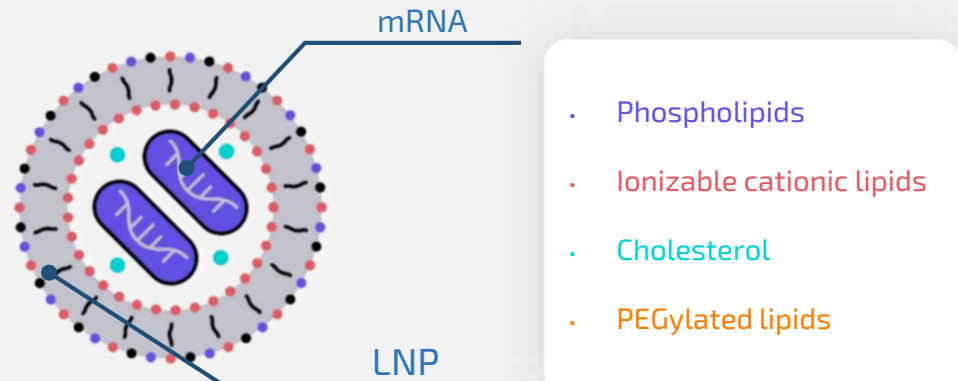


■ mRNA Platform (Core technology)

1) 5' Capping



2) LNP (Lipid Nano Particle) – Delivery vehicle

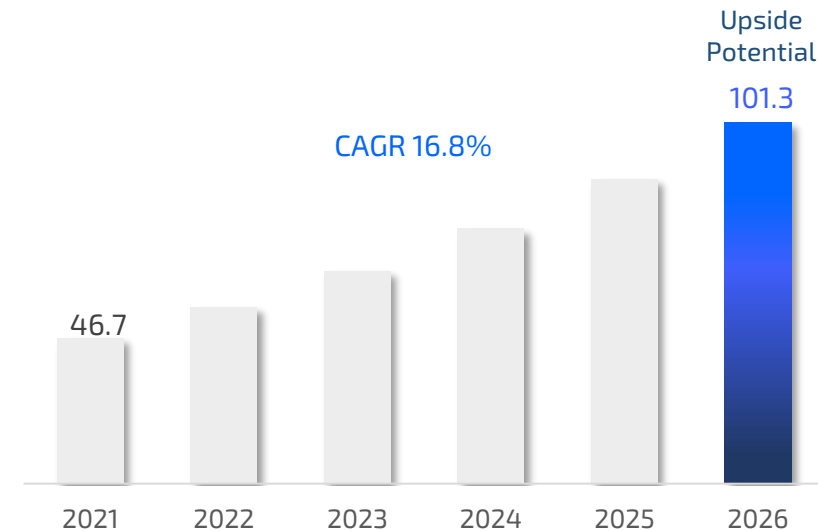


■ mRNA vaccines & therapeutics market

- mRNA technologies is the opportunity for rapid development and manufacturing against emerging pathogens, as demonstrated with Covid19 vaccines.
- Rapid drug development (Avg. 10 years ▶ 10 months)

mRNA 백신 및 치료제 시장 전망

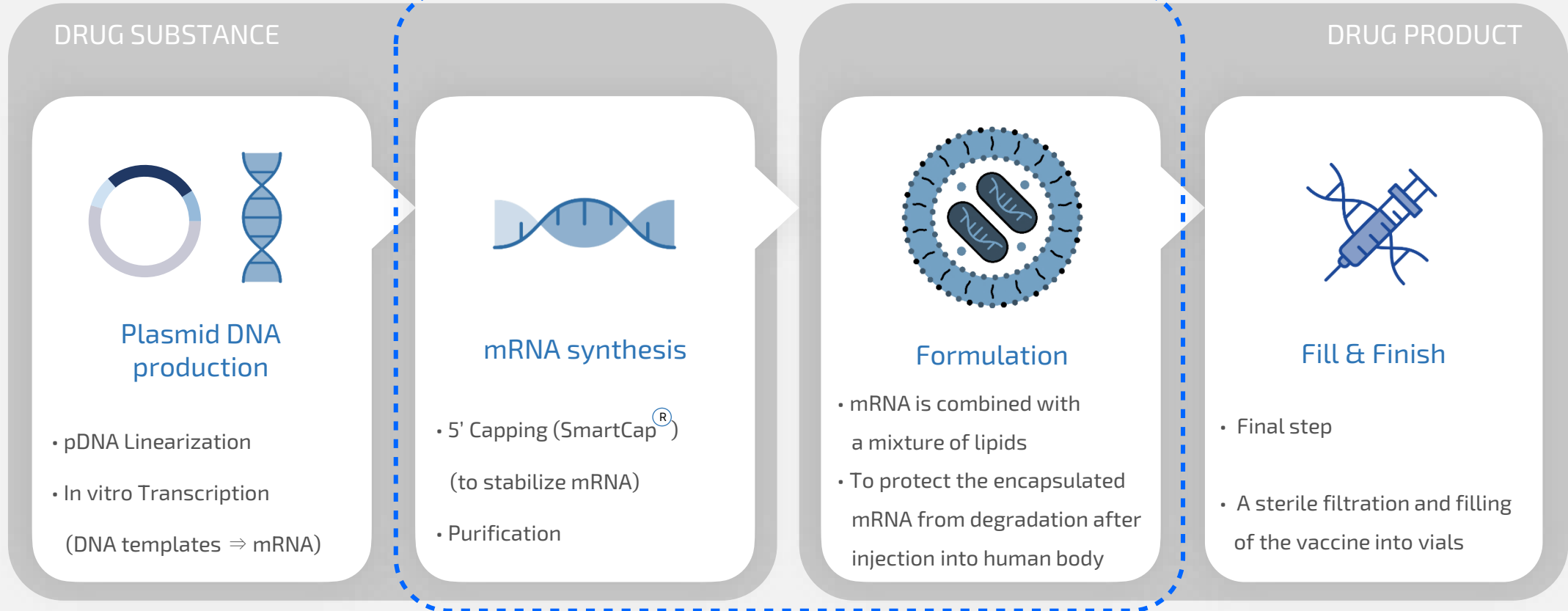
Billions(USD)



Source : ResearchAndMarkets



- mRNA vaccine / drug manufacturing process

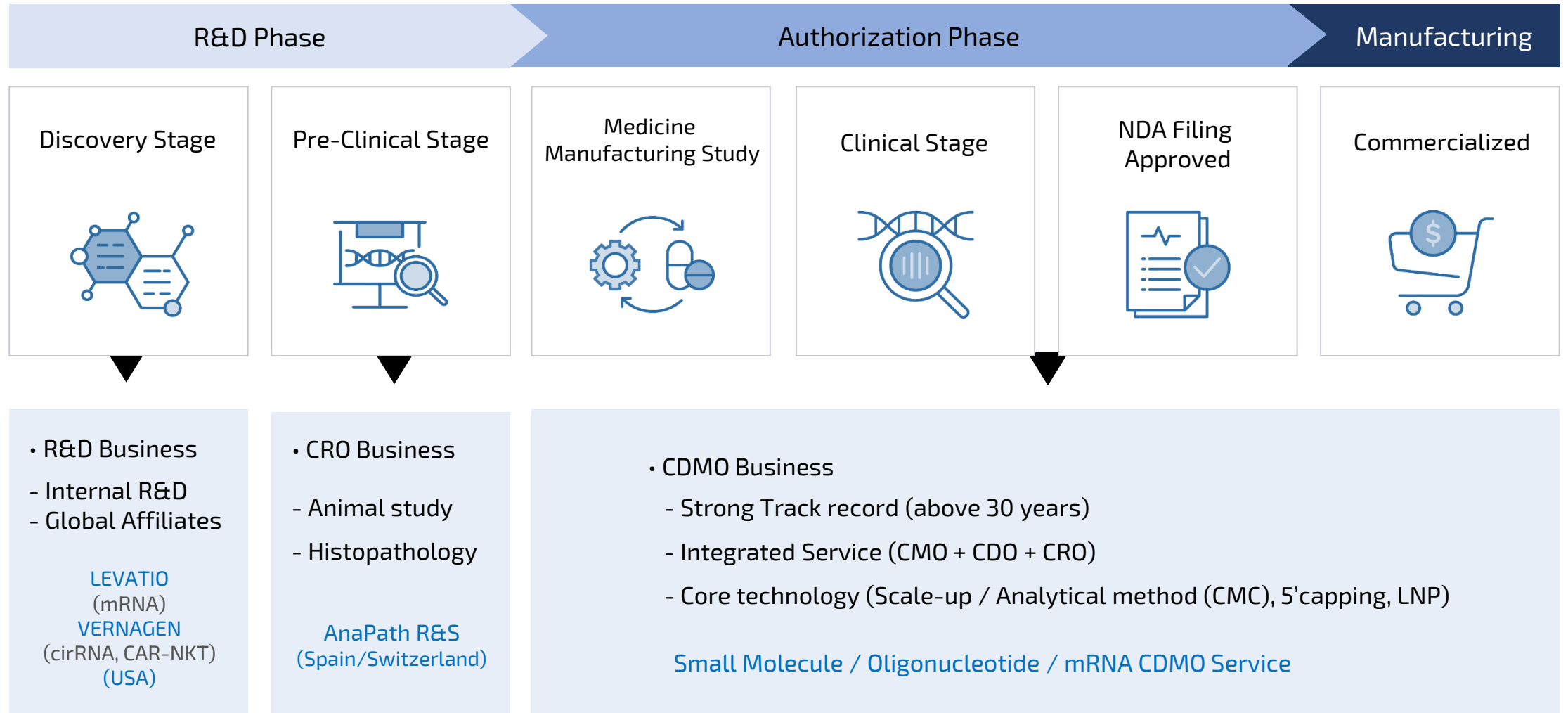


STPHARM connects all aspects of mRNA drug development to clinical and commercialized production



PART 03

Business Overview





ST PHARM's Core Strength (Oligonucleotide CDMO)

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

Manufacturing Capacity Expansion (disclosed)

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

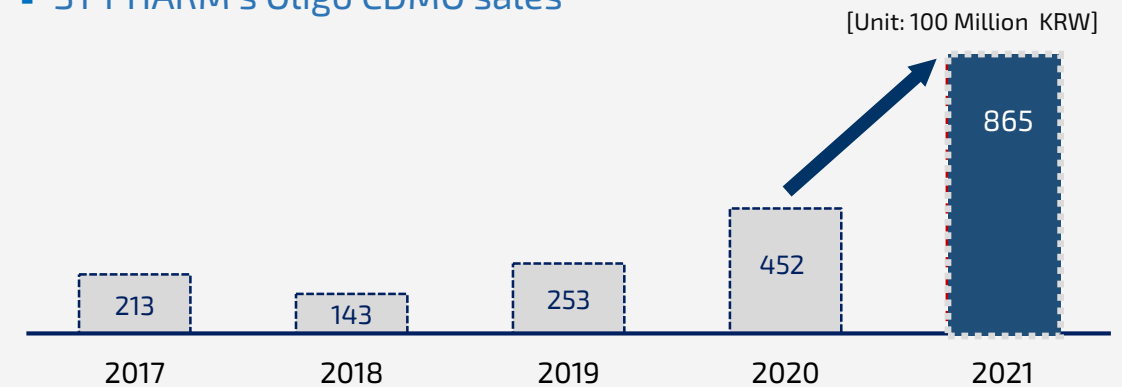
Strong Track Record

- '2018 & '2021 Global API Manufacturing(Oligonucleotide) Growth Excellence Leadership Award' from 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

Partner	Indication	Stage			
		Phase1	Phase2	Phase3	Commercial
Company A	Hyperlipidemia	●			
Company A	CVD	●			
Biotech	MDS / MF	●			
Company B	CVD	●			
Company C	Hepatitis B	●			
Company D	Hemophilia	●			
Company E	CVD	●			
Company F	Thrombus	●			

ST PHARM's Oligo CDMO sales

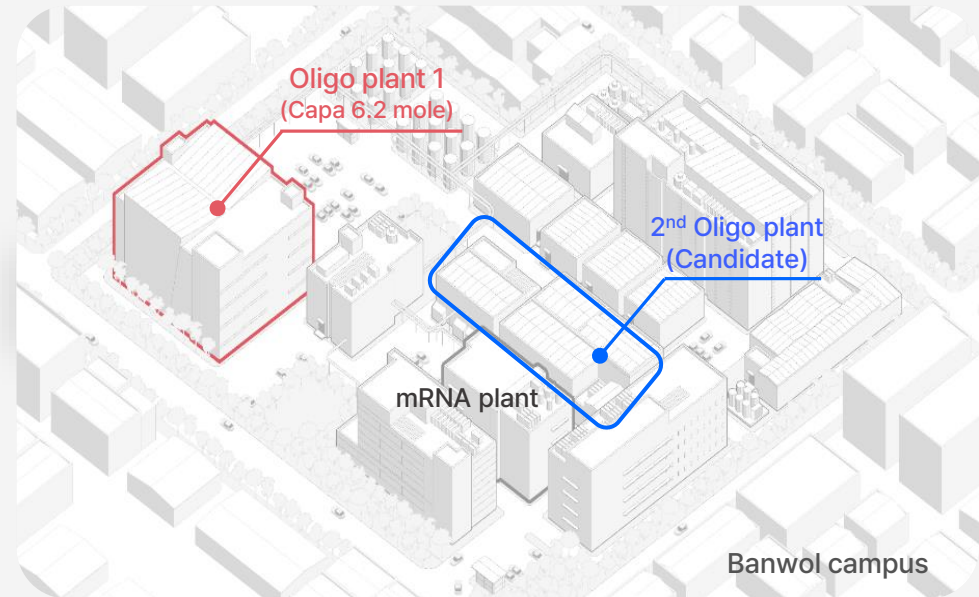
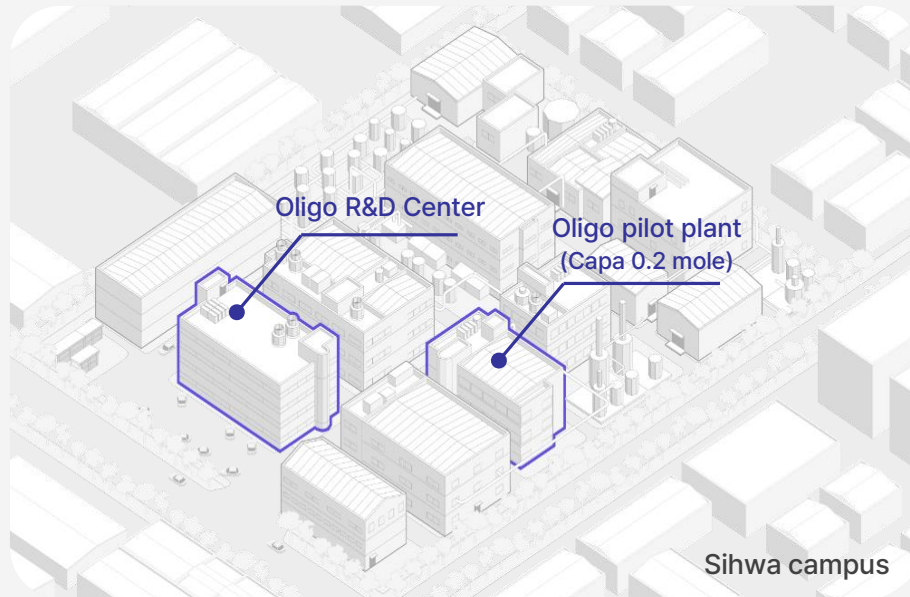




Capacity (Oligonucleotide)

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

Oligo production	Current	2022, 4Q	2024, 3Q	2026, 1Q
	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	2.0 mole	6.4 mole	10.2 mole	14.0 mole
	1.0 time	3.2 times	5.1 times	7.0 times





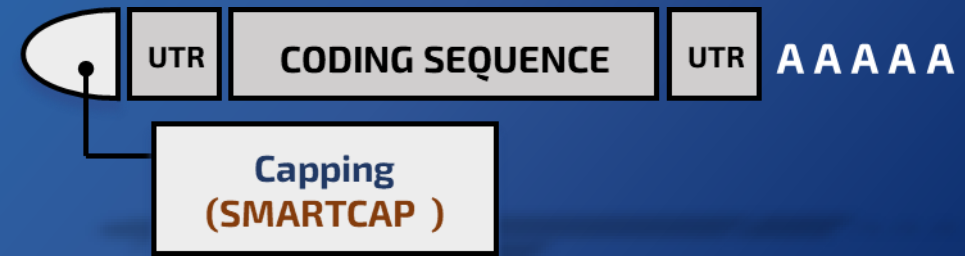
Core Technology

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™)



- SMARTCAP®

➤ SMARTCAP®

- 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



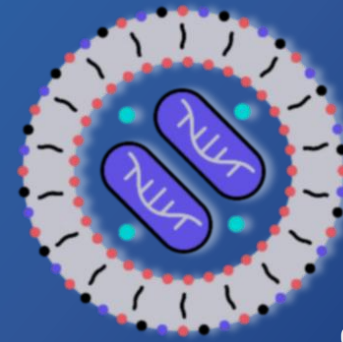
Core Technology

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™)



- STLNP™ / SMARTLNP™

STPHARM LNP Strategies

1. In-Licensing LNP

- Proven, unsurpassed technology (applied to Covid19 vaccine)

2. ST Pharm LNP (STLNP™)

- ST PHARM's own patented LNP ('2020)
- Platform for mRNA CDMO

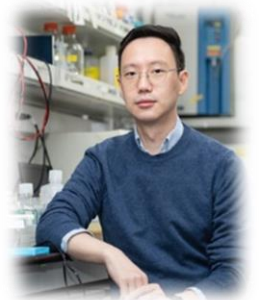
3. Next generation LNP (SMARTLNP™)

- Collaborations with E-HWA Women's Univ. in KOREA
- Improving stability and immune response

LNP study (collaborations with academies)

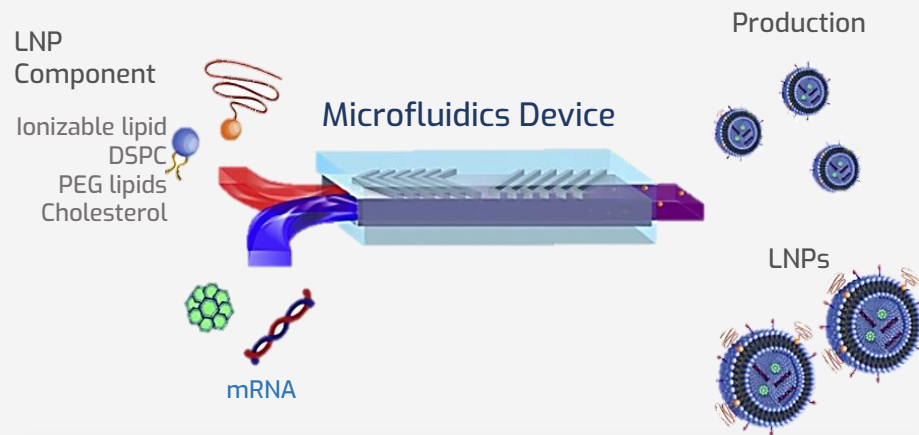
Collaboration with Prof. Hyuk-jin Lee ('21.03)

- 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)





➤ Production technology for mass production (Microfluidics)



“Collaboration with Korean company”

- Essential facility for mRNA mass production (Microfluidics)
- Apply to mRNA therapeutics
- **Capacity**
 - single reactor (amount) : 2.0 g/day
 - 8 reactors (amount) : 15.9 g/day

➤ Collaboration with Korea company (2021.09)

- A novel technology based company (Specialized in DDS)
- The only manufacturer of microfluidics
- Their own patented manufacturing technology (IVL-PPFM[®])

“Advanced technology (A parallel microfluidic channels)”

- > more than 1.5 times higher (production rate)
- > expanding 450 channel (in development)

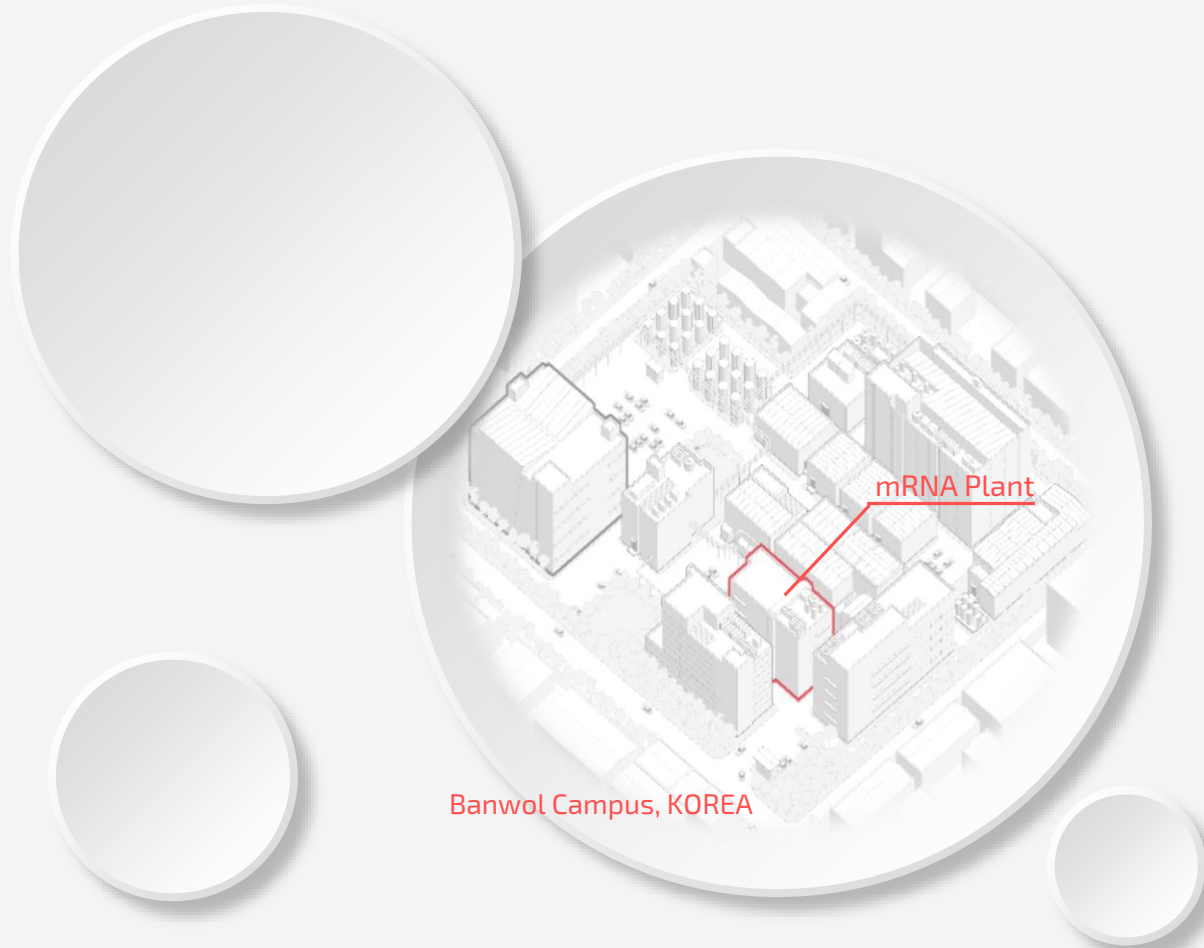
➤ Advisory board (Pro. Dong-Pyo Kim)

- Center for Intelligent Microprocess of Pharmaceutical Synthesis
- The world renowned scientist
- Development of microfluidics with ST PHARM





“ From milligram to kilogram scale production”



➤ 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*



In 2019, Acquired Global CRO company in Europe (Client-dependent CMO \Rightarrow Client-leading CDMO)
A completion of restructuring in 2020, expecting to turn-around since 2021

▪ AnaPath Research (Barcelona, Spain)

- History : Established in 1986 (Envigo, Spain)
(AnaPath acquired in Nov. 2019)
- Building : 10 thousands sqm, Land : 20 thousands sqm
- Rooms (more about 800 animals (e.g. monkey, rabbit, dog))

▪ AnaPath Service (Basel, Switzerland)

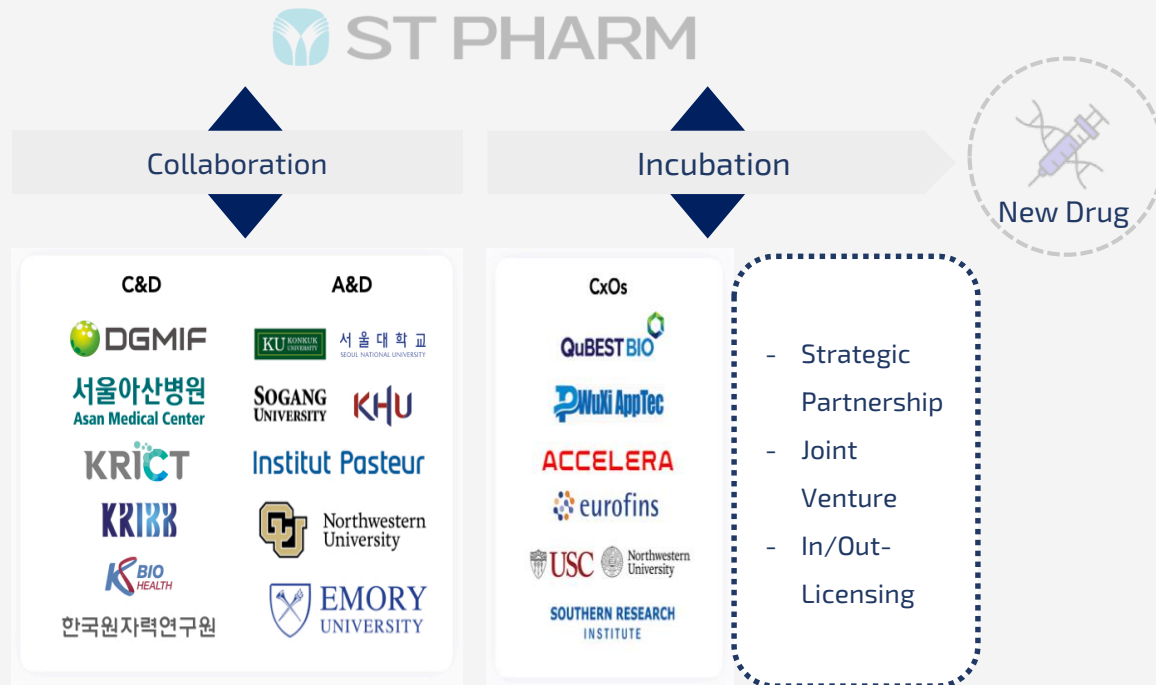
- CSO : Klaus Weber (Specialized in histopathology)
- The biggest non-clinical CRO in Europe
- Approval of **GLP (In 2006)**, Join EU Safety Alliance
- Up to 1000 experiments (chronic toxicity, carcinogen) by using animals





ST PHARM Virtual R&D

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



ST PHARM Pipeline

"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 (Erbixux)

Pipeline (Indication)	Partner	Stage		
		Discovery	Pre-clinical	Phase1
STP0404 (Anti-AIDS)	Emory Univ. Colorado State Univ.	[Progress bar]		
STP1002 (Anti-Cancer (Colorectal))	Asan Hospital	[Progress bar]		
STP2104 (Covid19 vaccine)	In-house	[Progress bar]		
NASH	Korea Research Institute of Chemical technology	[Progress bar]		
Oral Heparin	B&L Deli Pharm	[Progress bar]		
Anti-virus	KRICT & Institut Pasteur Korea	[Progress bar]		
Others (2)	Undisclosed	[Progress bar]		



▪ LEVATIO Therapeutics (San-Diego, USA)

- Establishment in San Diego (USA) for mRNA & CAR-NKT
- With ST PHARM's novel mRNA platform technology
- Entry into the field of gene, cell therapeutics

▪ Technology

- mRNA (ST PHARM's technology) + CAR-NKT (Levatio)
- Cell therapeutic using 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
(the 4th Lymphocyte)
 - * Suitable for mass production (Off-the-shelf)
 - * Activating immune system (Adjuvant)

First-in-Class mRNA Therapeutics

- Development of first-in-class mRNA cancer vaccine and customized neo-antigen vaccine
- 'Off-the-Shelf' CAR-NKT cells engineered with mRNA



Proof-of-Concept (POC)

- Strong data-driven POC modality validating potential of proprietary mRNA technology and therapeutic application



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



PART 04

Financial Overview



Achieved record high results in 2021 : **Sales up 33.4%, +41.4 BN KRW (YoY)** driven by Oligo business & CRO

* Detailed oligo project sales : Hyperlipidemia 32.5 bn, HTT 16 bn, Monomer 13.8 bn, etc

■ P/L (Consolidated)

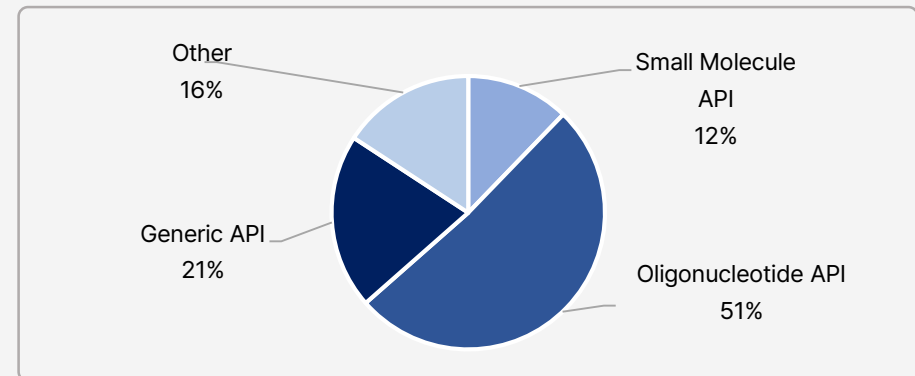
[Unit : Million KRW]

	2021	2020	2019
Sales	165,642	124,109	93,257
COGS	107,899	104,123	94,885
Gross Profit	57,743	19,985	-1,628
SG&A	52,165	38,802	25,075
Operating Profit	5,578	-18,817	-26,703
Net Income	3,377	-13,154	-18,529
OCI	1,765	504	-328
CI	5,142	-12,650	-18,856

■ Sales breakdown

[Unit : 100 Million KRW]

Business	2021	2020	2019	YoY
Small Molecule API	179	154	118	16.23%
Oligonucleotide API	865	452	252	91.37%
Generic API	356	477	457	-25.37%
Other	267	157	105	70.1%
Total	1,656	1,242	933	33.3%





■ B/S (Consolidated)

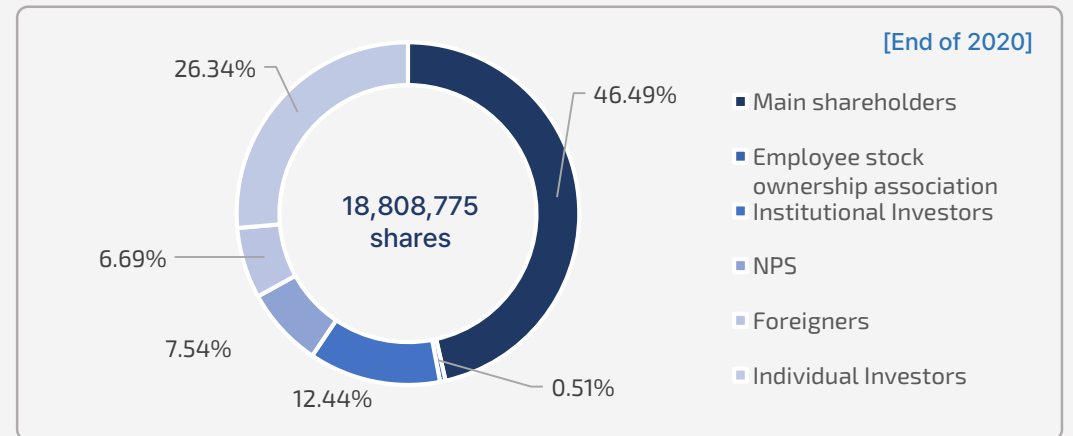
[Unit : Million KRW]

	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, %]

	Shares	Ratio	Note
Dong-A Socio Holdings	6,096,552	59.9%	Majority holder
Jung-Seok Kang	2,475,657	24.3%	Major holder of Holdings
Soo-suk culture foundation	171,600	1.7%	Foundation
NPS (National Pension Services)	1,417,609	13.9%	
Kyung-Jin Kim & 3 holders	9,507	0.1%	Board members
Total	10,170,925	54.1%	



Thank You

ST PHARM

Technology-Driven Gene therapy CDMO
From Oligonucleotide to xRNA

