



Game Changer based on Science & Technology

Technology-Driven Gene Therapy CDMO Business: From Oligonucleotide to mRNA

ST PHARM IR Book

May. 2021

I . Company

II . Business

1) ST PHARM Business

2) Family Business

- AnaPath Service & Research
- Levatio Therapeutics

III . Financial figures

IV . Appendix

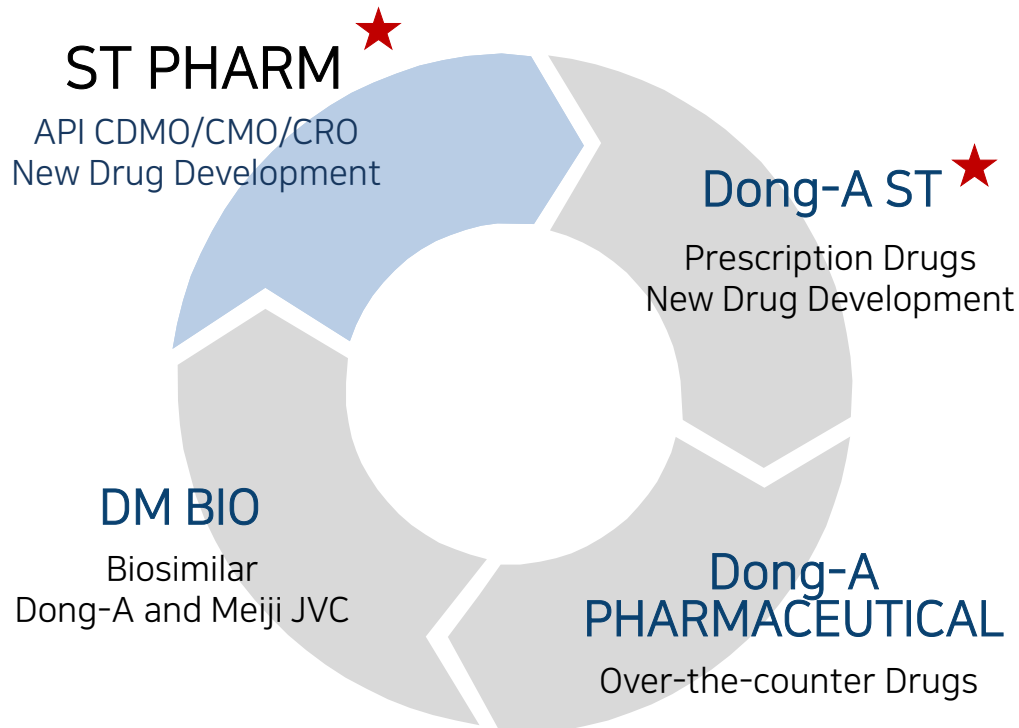


DONG-A SOCIO HOLDINGS

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

Healthcare

Non-Healthcare



Dong-A OTSUKA

Food and Beverage
Dong-A and Otsuka JVC

YONGMA LOGIS

Logistics and Storage

SOO SEOK

Bottles Manufacturing

DA INFORMATION

IT Business and Solutions

MISSION


Infinite challenge for a human being with happiness & health

ST PHARM VISION 2025

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




CORE VALUES




Innovation

Start from small innovations in a new perspective




Transition

Drive change by reading the trend



Trust

Build trust generate greater synergy



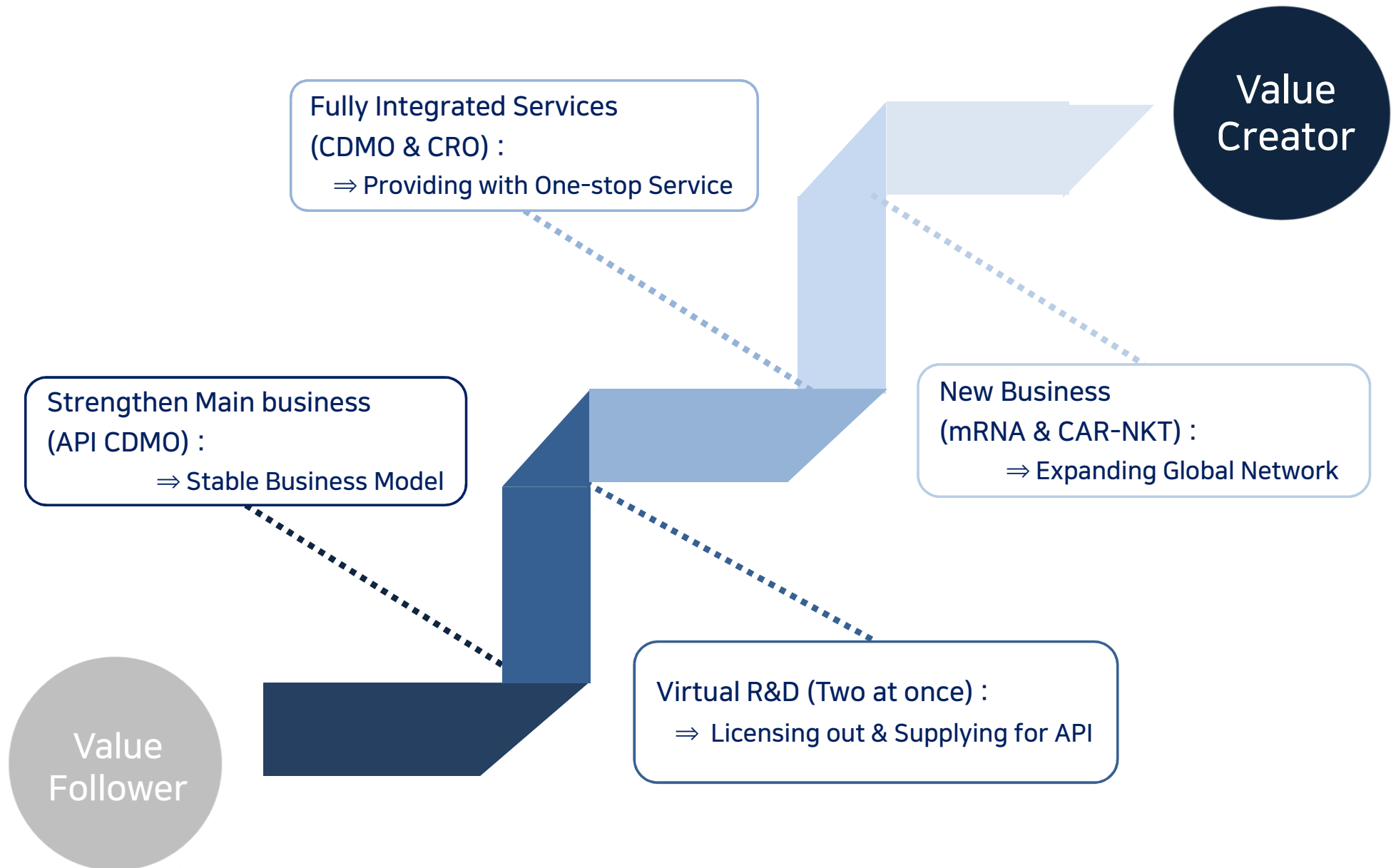
Thrive together

Grow with employees, customers and society



Green Management.

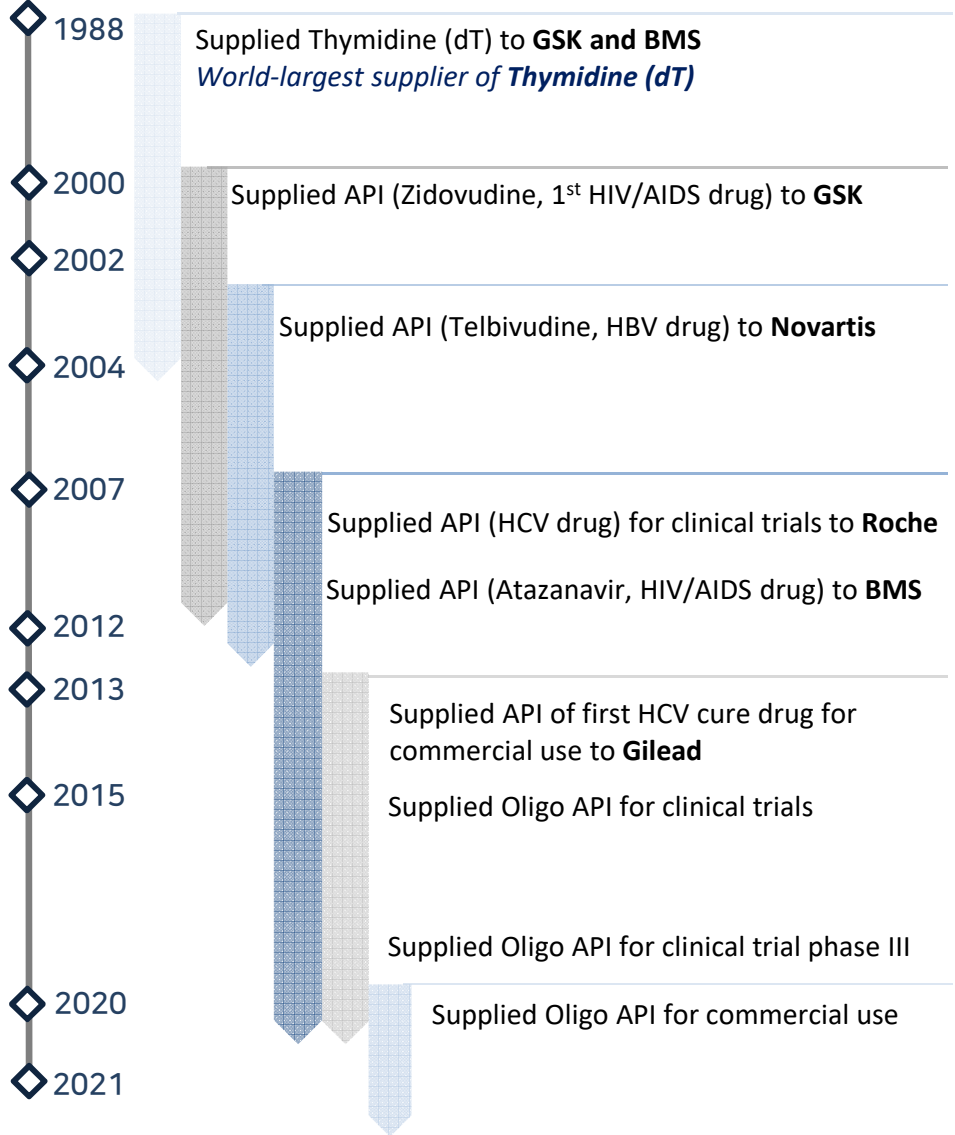
Manufacture eco-friendly for our better environment



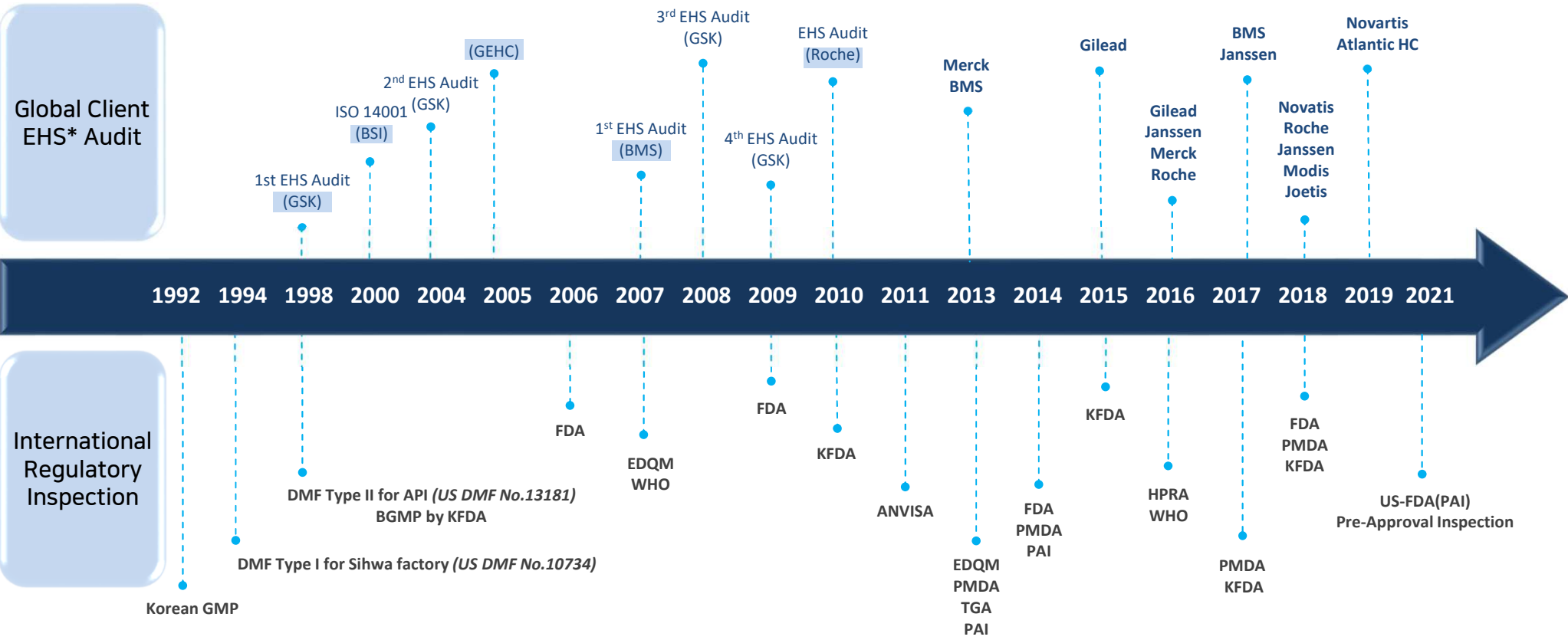
Company Record (Milestone)

1983	Establishment <i>Samchully Pharm</i>
2010	Became a subsidiary of Dong-A Socio Group (Corporate name changed to ST PHARM)
2012	Nominated as <i>Innovative Pharmaceutical Company</i>
2013	Selected as ' <i>Advanced Technology Center</i> ' (ATC)
2014	TGA (Australia) cGMP certification
2015	Establishment of second manufacturing site (<i>Ban-wol site</i>) FDA cGMP certification and PMDA cGMP certification
2016	EU cGMP certification, IPO in KOSDAQ (KOSDAQ: 237690) Awarded for \$100,000,000 of exportation Presidential Award for <i>Innovative Company</i>
2018	Strategic expansion of Oligonucleotide (Oligo) Honored with 'Global Growth Excellence Leadership Award' (Frost & Sullivan)
2019	Non-clinical animal safety CRO service started - AnaPath Services (Switzerland) & AnaPath Research (Spain) Approval of STP1002(Anti-Drug) Phase1(USA) IND Roche CDMO Award 2019
2020	Approval of STP0404(AIDS) Phase1(EU) IMPD Expansion of Oligo plant (1 st : 0.8t scale / 2 nd : 0.3t scale) mRNA business started
2021	Establishment Levatio Therapeutics (mRNA & CAR-NKT R&D Center) Mid-scale mRNA GMP facility in Banwol Campus (<i>In May</i>)

Supply Record



* EHS : Environmental, Health & Safety



Successfully inspected by



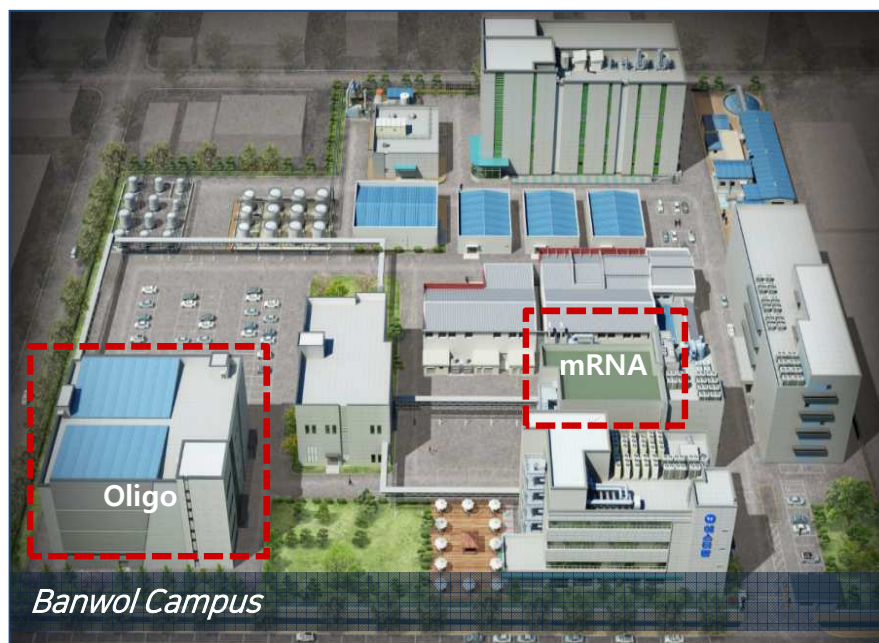


General Capacity	Sihwa	Banwol	TOTAL
Area	16,400 m ²	28,220 m ²	44,620 m ²
Reactors	67	58	125
Capacity	286,100 L	139,000 L	425,100 L

Small Molecule	Sihwa	Banwol
Commercial Plant	3,000 ~ 7,000 L	3000 ~ 7,000 L
Kilo/Pilot Plant	Kilo: 50 ~ 100 L Pilot: 200 ~ 500 L	Kilo: 100 L Sector 3/4: 500 ~ 2,000 L

Oligo Plants	Sihwa	Banwol
Small scale	(nmol ~ μmol scale): MM-192, MM-12	
Mid scale	(mmol scale): 3x OP100	
Large scale	(300mmol scale): 2 x AKB	(1.5mole scale) : 1xGE above(4.6 mole scale): <i>(In 2022)</i>

※ Oligo Capa: 3.5 X the current capa, Global No.1 (6.4mol, in 2022)



Seamless development from manufacturing to non-clinical animal safety service
Gene therapy CDMO business from oligonucleotide to mRNA

AnaPath Services

Basel, Switzerland (41 FTE)

- Histopathology service

AnaPath Research

Barcelona, Spain (120 FTE)

- Non-clinical animal safety assessment

ST PHARM

South Korea (517 FTE)

- Seoul Office, Sihwa and Banwol Campus
- API CDMO service

LEVATIO

San Diego, USA

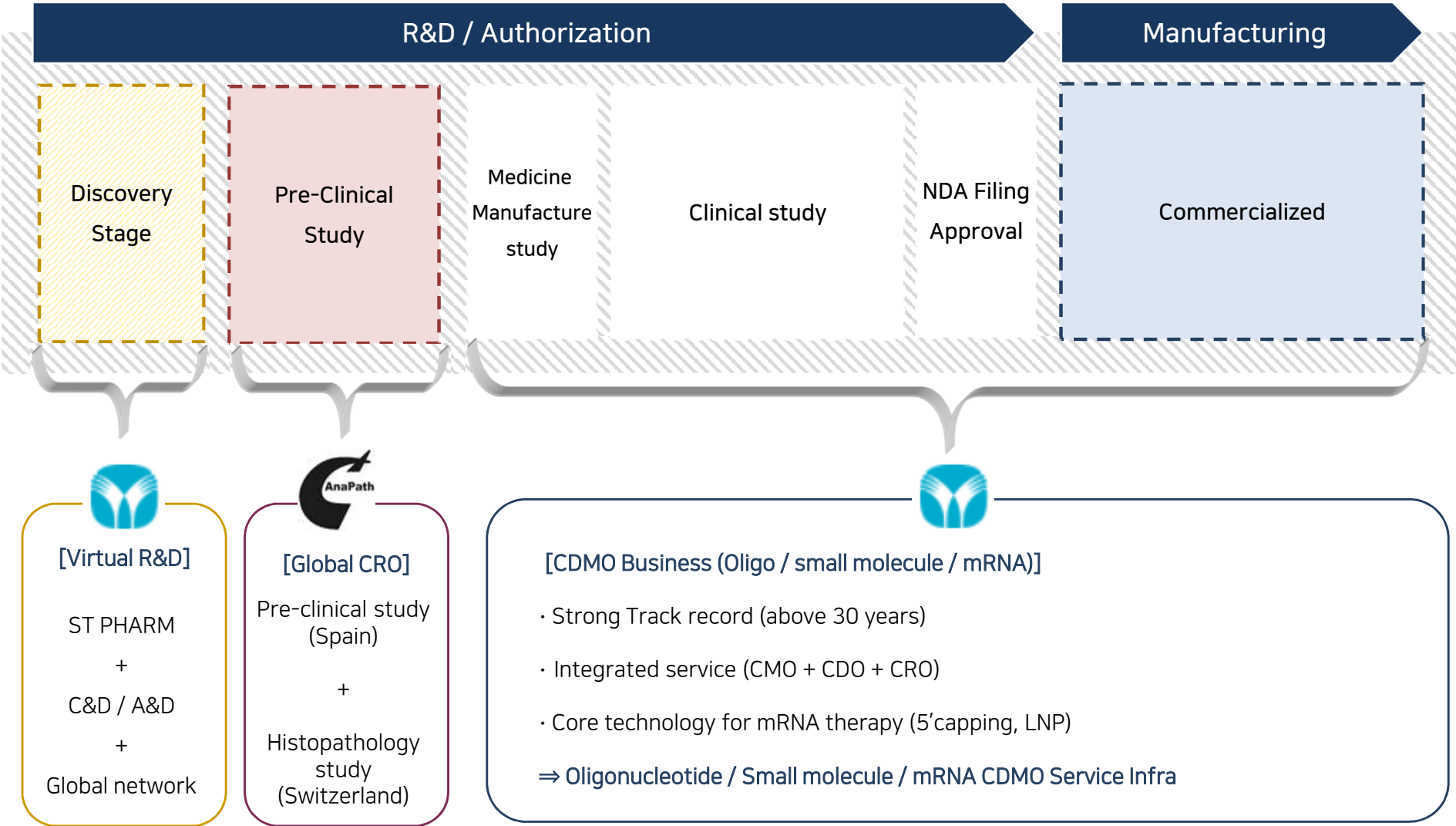
- mRNA & CAR-NKT R&D

STP America Research

Delaware, USA

- USA Headquarters of ST Pharm

ST PHARM, Technology-Driven Therapy CDMO Business (From Oligonucleotide to mRNA)




With the advent of platform technology (Gal-Nac), growing number of RNA drugs pipelines in Global market
 Expecting a number of RNA therapeutics starting from Inclisiran ⇒ **Rapid increase in demand of Oligo**

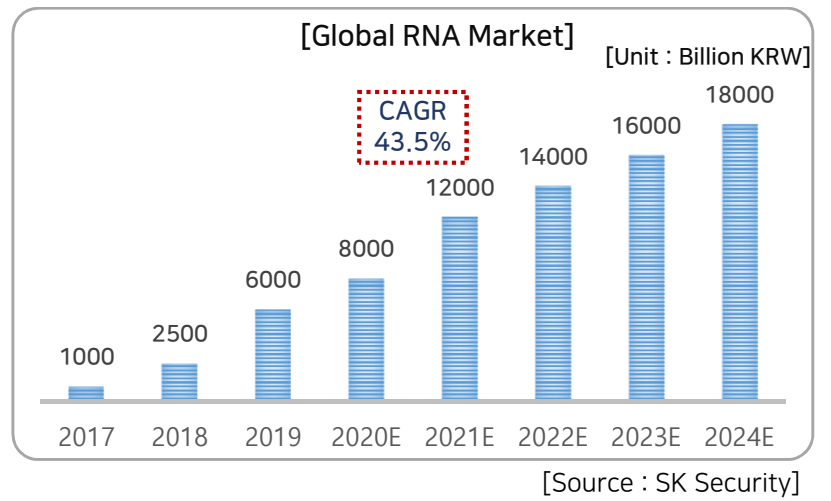
1. RNA therapeutics Overview 2. RNA therapeutics Market 3. STPHARM Oligo Business

Beginning for RNA Area

- Global RNA therapeutics market : \$0.8B (In 2017) ⇒ **\$1.6B (Expected In 2024)**
- Target cell Expansion : from rare to chronic disease
 (ex. Gal-Nac (Liver cell-penetration platform))

RNAi Global Pipeline

- Global RNAi Technology Company  



[RNA based therapeutics for Chronic disease]

Around one in five people worldwide are at increased risk of developing CVD due to Lp(a)¹

An estimated 1.4 billion people globally have elevated Lp(a) levels >50 mg/dL²

AKCEA-APOCIII-L_{Rx}
One product, multiple indications targeting elevated triglycerides

Familial Chylomicronemia Syndrome ~3-5K patients globally ³	Severe High Triglycerides (>500mg/dl) >10M patients globally ² Leading cause of pancreatitis and increased risk for cardiometabolic diseases	High Triglycerides (150 - 500mg/dl) ~50M patients globally ² Increased risk of pancreatitis and stroke
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AROHBV1001: Effect of JNJ-3989 and NA treatment on HBsAg

RNAi Therapeutics to Reimagine Treatment of Hypertension
Opportunity for Tonic Blood Pressure Control

Disease Overview

Primary Hypertension¹ ~108 Million in U.S.	Hypertension at high CV risk² ~38 Million in U.S.
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>71% of patients have uncontrolled hypertension (>130/80 despite treatment)³
 Hypertension risk further exacerbated by variability in BP control, lack of nighttime dipping, and poor medication adherence
 Together, contribute to substantial risk of CV morbidity and mortality

Potential Complications of Uncontrolled Hypertension

[Source : each company]

[Commercialized RNA pipeline]

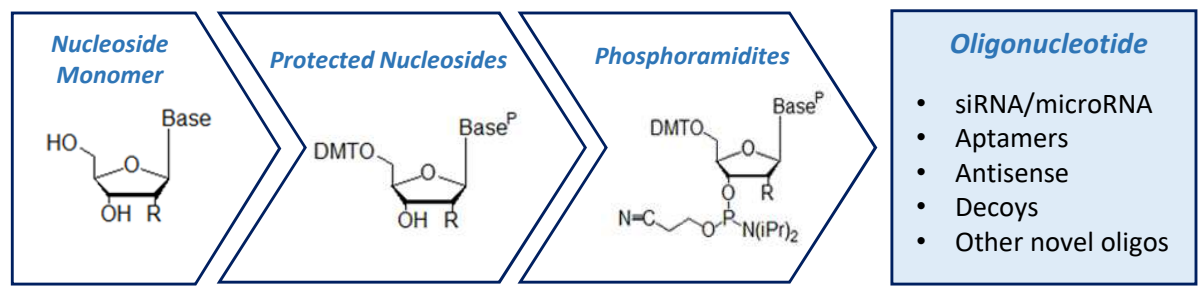
Type	Name	Indication	Company	Date
ASO	Exondys51	DMD	Sarepta	16.Sep
ASO	SPINRAZA	Spinal Muscular Atrophy	Biogen	16.Dec
ASO	Tegsedi	hATTR	Ionis	18.Oct
siRNA	Onpattro	hATTR amyloidosis	Alnylam	18.Aug
siRNA	Givlaari	Acute Liver Failure	Alnylam	19.Nov
ASO	Vyondys 53	DMD	Sarepta	19.Dec

[Source : each company]

Based on Global Track Record, Having a fully Integrated In-House Production Capability
 Demonstrated the superiority of **Global level-Oligo business** (Roche CDMO Award 2019)

1. RNA therapeutics Overview 2. RNA therapeutics Market **3. STPHARM Oligo Business**

- The only simultaneous manufacturer of monomer & oligo in global market

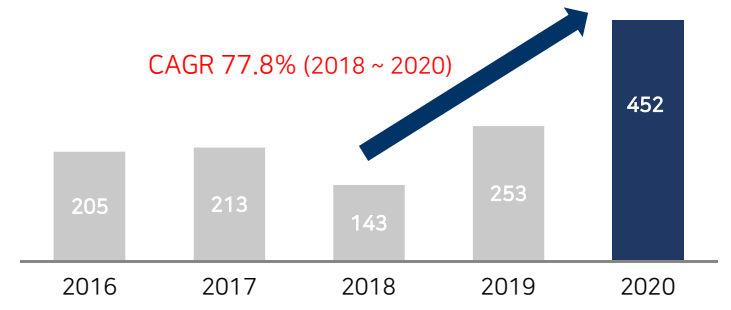


- Innovative Manufacturing System & Platform**
 - Supplied nucleoside-API for global pharma since 1980's
 - The first production of oligo based on GMP in 2008, around the world.
 - World's only monomer/oligo "one-stop" manufacturing system
 - Excellent experiences with authorized global pharma & quality system
- Strong Track Record**
 - **Well-established tech transfer and scale up production** with 15 years experience for over 20 GMP oligos manufactured including Phase II/III uses for US and Europe clients
 - Selected as **Asia-Pacific's Top Oligonucleotide API Manufacturer** and Korea's first company to be awarded with '2018 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 Oligo New drug Pipeline** [Part of the pipeline]

Partner	Indication	Pre Clinical	Phase I	Phase II	Phase III	Commercial
Global A	Dyslipidemia	[Progress bar]				
Global A	Atherosclerosis	[Progress bar]				
Global B	MDS / MF	[Progress bar]				
Global C	CVD	[Progress bar]				
Global D	Hepatitis B	[Progress bar]				
Global D	Immunity booster	[Progress bar]				
Global E	Hemophilia	[Progress bar]				
Global F	CVD	[Progress bar]				
Global G	Thrombosis	[Progress bar]				

- ST PHARM Oligo CDMO Sales** [Unit : 0.1 Billion KRW]



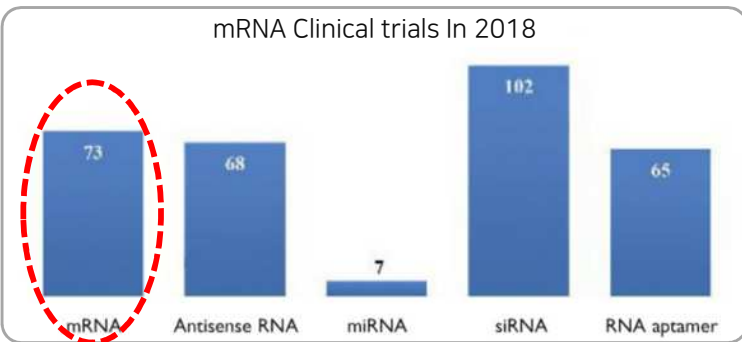
Expecting mRNA vaccine & therapeutics market growth from \$9.41B in 2021 to \$15.49B in 2026 (CAGR 10.5%)
 Due to COVID-19 Pandemic effect, Accelerated development of mRNA vaccines and their approvals.

1. mRNA Overview

- mRNA**
 - Stability/ Efficacy : Non-infective, specific targeting
Less genome Integration
 - Productivity : Rapid & Economical (Scale-up) production
Simple manufacturing (Nucleic Sequencing)
 - Universe Platform
⇒ Adapting the vaccine for cancer
Replacing antibody drug, gene therapy

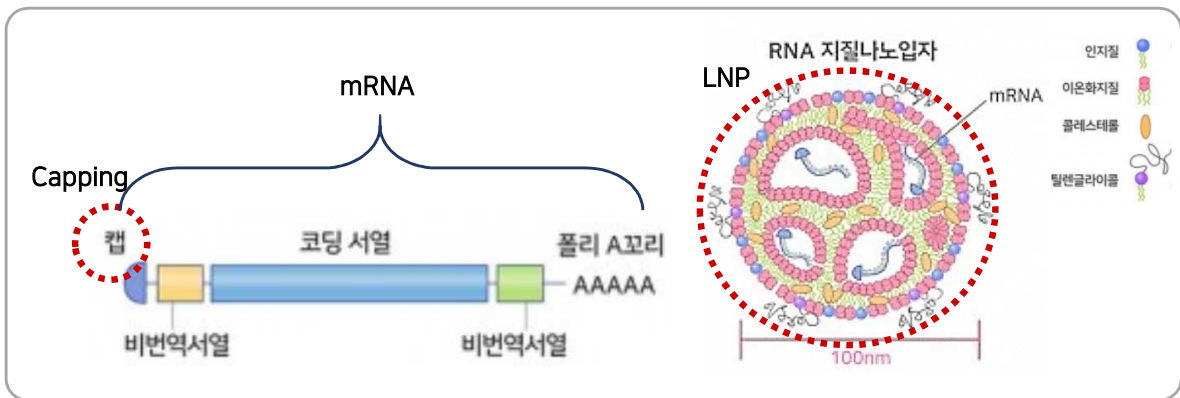
mRNA Vaccine

- Excellent Efficacy : preventive effect (above 90%) In Phase3
- Flexibility (Control of production amount)
- Stability (Not using virus vector)



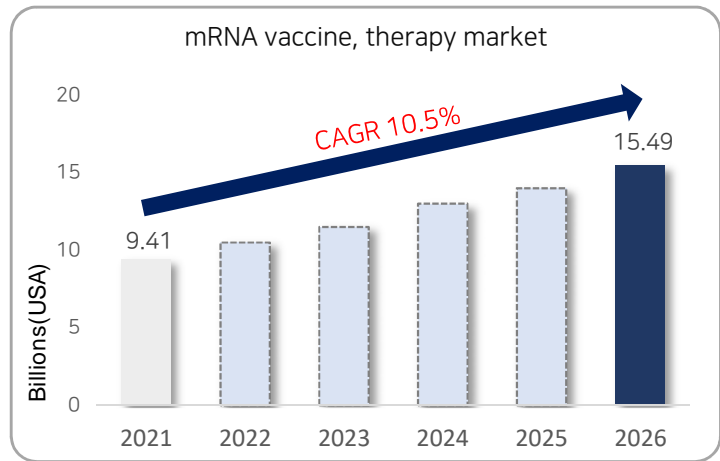
2. STPHARM mRNA Business

- mRNA Platform (Core Tech) : 1) 5'Capping, 2) LNP (Lipid Nano Particle)**



- mRNA Vaccines & Therapeutics Market**

- Accelerated development due to **COVID19 Pandemic**
- Increase in the prevalence of chronic disorders and infectious diseases
- Significant increase in **licensing agreement** between pharmaceutical manufactures

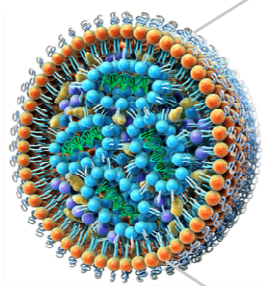


Source : Imarcgroup

ST PHARM established core technology for mRNA vaccines & therapeutics 1) 5' Capping, 2) LNP Platform
Continuing to expand mRNA plant (mRNA synthesis from milligram to gram scale production)

1.mRNA Overview 2. STPHARM mRNA Business

- mRNA Platform (Core Technology)
 1. 5' Capping Reagent (Smart CAP™)
 - Novel cap analogues for IVT mRNA (Strong IP position)
 - Ample nucleotide manufacturing experiences (Cost-effective)
 2. LNP (Lipid Nano Particle)
 - Advanced delivery system (delivering mRNA into specific cells)
 - ST PHARM is running 3 different LNP Platform strategies



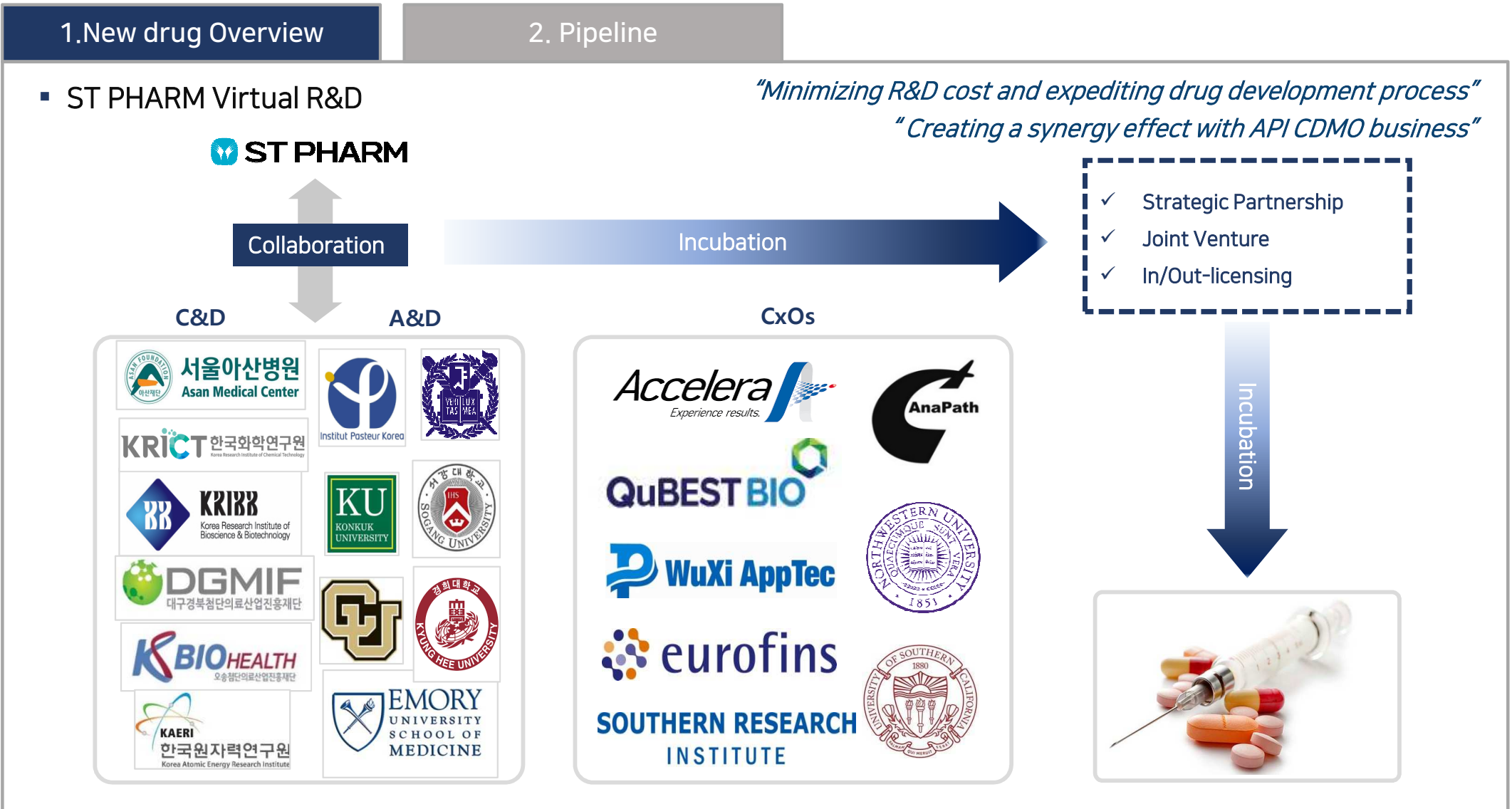
- ST PHARM LNP Strategy
 - 1 In-licensing LNP
 - Proven, unsurpassed technology
 - Applied to Covid19 vaccine
 - 2 ST PHARM LNP (SMART LNP™)
 - ST PHARM's own patented LNP
 - Platform for mRNA CDMO
 - 3 3rd generation LNP
 - Collaborations with academies in KOREA
 - Improving stability and immune response

- mRNA GMP facility Expansion (from mg to g scale)
 - 1st Stage. R&D / small-scale (non-GMP)
mRNA Plant (1F, Banwol Campus) : Established on Aug. 2020
mRNA R&D and small-scale production for non-clinical animal study
 - 2nd Stage. Mid-scale (GMP)
mRNA Plant (1F, Banwol Campus) : Expansion of mRNA manufacturing facility (*Completion: May 2021*)
Capacity : Milligram to multi-gram/month
 - 3rd Stage. Large or commercial-scale (GMP)
mRNA Plant (3F,5F, Banwol Campus) : Further expansion
Capacity : 100-120 g/month (up to 10million doses*)
Customized facility available as per client's request

** CureVac vaccine-babased (12 ug/dose)*



ST PHARM Virtual R&D Strategy to minimize R&D cost and expedite drug development process



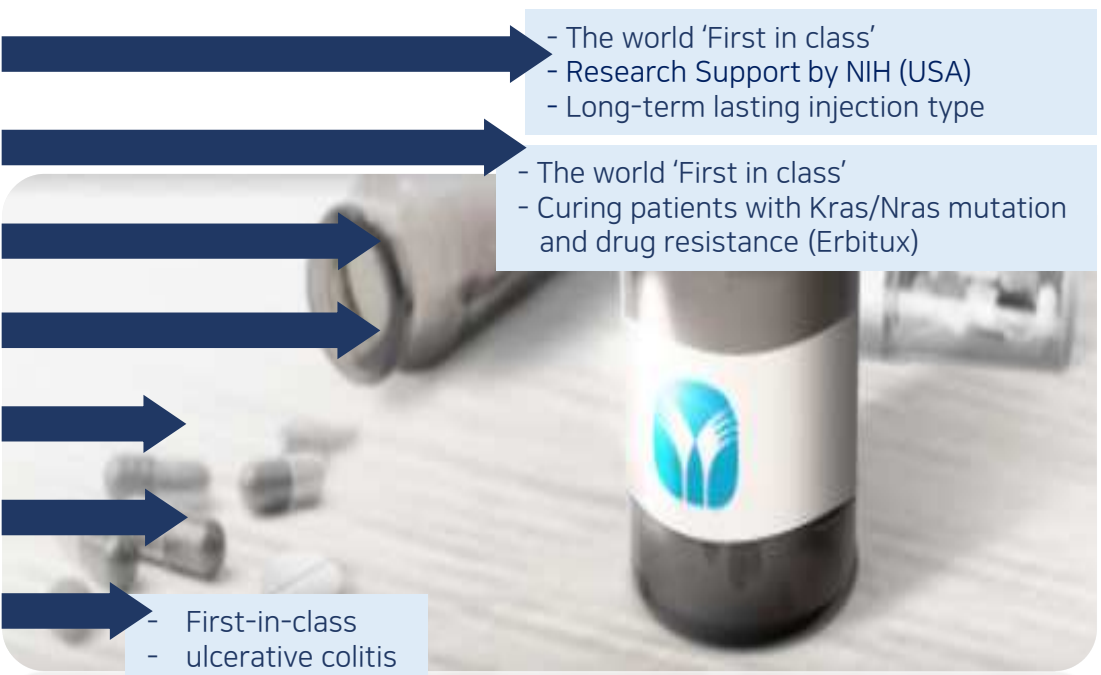
ST PHARM has world-class two pipelines ('First in class') 1) AIDS therapeutic, 2) Colorectal cancer therapeutic

1. New drug Overview

2. Pipeline

ST PHARM's New drug Pipeline

Pipeline	Partner	Stage				
		Discovery	Pre-clinical	Phase 1	Phase 2	Phase 3
STP0404 (AIDS)	Emory Univ. Colorado State Univ.	<ul style="list-style-type: none"> - The world 'First in class' - Research Support by NIH (USA) - Long-term lasting injection type 				
STP1002 (Colorectal cancer)	Asan Hospital (KOREA)	<ul style="list-style-type: none"> - The world 'First in class' - Curing patients with Kras/Nras mutation and drug resistance (Erbixux) 				
NASH	Korea Research Institute of Chemical technology					
Oral Heparin	SNU (KOREA) B&L Deli Pharm					
Influenza Virus	OncoCross					
Anti - virus	KRICT & Institute Pasteur Korea					
Others (2 projects)	Undisclosed	<ul style="list-style-type: none"> - First-in-class - ulcerative colitis 				



In 2019, Acquired Global CRO company in Europe (Client-dependent CMO ⇒ Client-leading CDMO)

A completion of restructuring in 2020, expecting to turn-around since 2021

1. Anapath R&S

2. Levatio Therapeutics

■ Anapath Research & Service (reason for acquisition)

- Rapidly Increased Biotech companies (increase in demand of CRO/CMO)

■ Anapath Research (Barcelona, Spain)

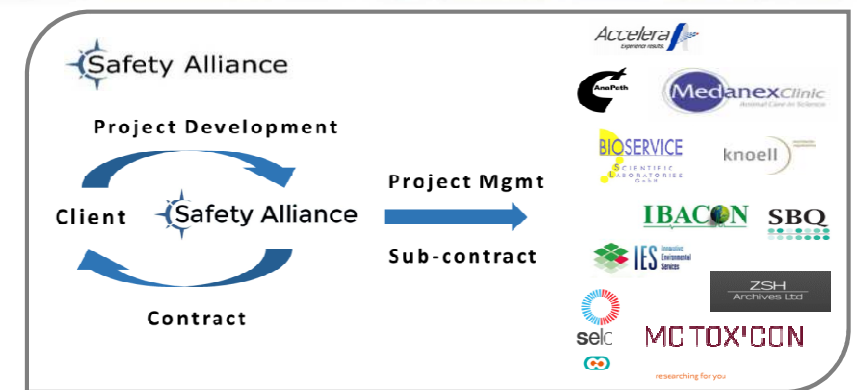
- Established in 1986 (Envigo, Spain)
- Anapath acquired in Nov. 2019
- Building : 10 thousands sqm, Land : 20 thousands sqm
- Rooms (more about 800 animals (e.g. monkey, rabbit, dog))

■ 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

■ Synergy with ST PHARM

- From pre-clinical to commercial phase (Integrated service) (CMO, CMC, AMV/AMT, etc.) Differentiated service
- New Drug Development + CRO + CDMO (synergy effect) maximizing the potential client pool



On Apr, Established Levatio Therapeutics developing next generation of cancer vaccine and CAR-NKT cell to treat cancers and autoimmune diseases

1. Anapath R&S

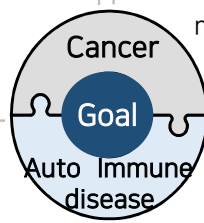
2. Levatio Therapeutics

■ Foundation of Levatio therapeutics

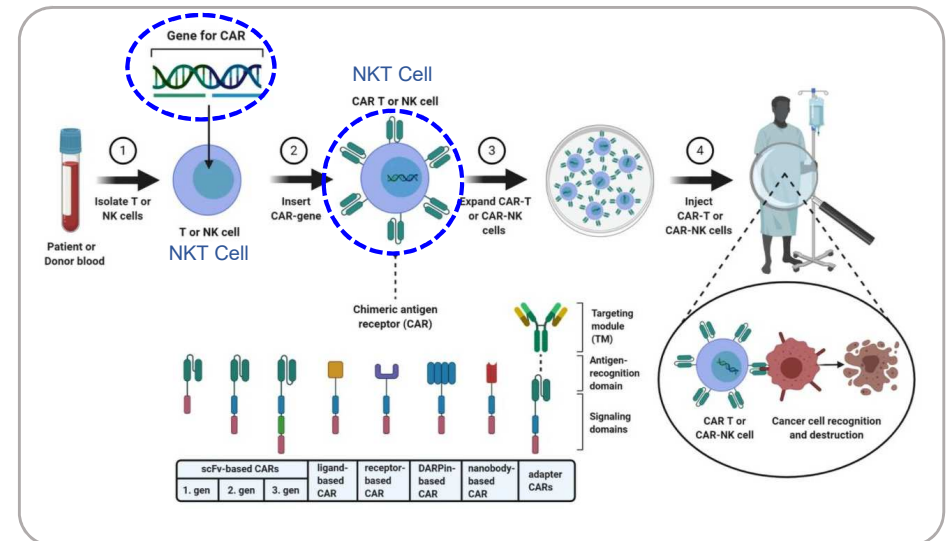
- Establishment in San Diego (USA) for mRNA & CAR-NKT
- With ST PHARM's novel mRNA platform technology
- Entry into the field of gene, cell therapeutics

■ Levatio's Goal

First-in-Class mRNA Therapeutics	Proof-of-Concept (POC)
<ul style="list-style-type: none"> - Development of first-in-class mRNA cancer vaccine and customized neo-antigen vaccine - 'Off-the-Shelf' CAR-NKT cells engineered with mRNA 	<ul style="list-style-type: none"> - Strong data-driven POC modality validating potential of proprietary mRNA technology and therapeutic application
<ul style="list-style-type: none"> - mRNA platform technology for developing cancer vaccines and 'Off-the-Shelf' CAR-NKT cells - Cancer and autoimmune disease 	<ul style="list-style-type: none"> - Open innovation strategy w/ academy, hospital, and research institute - Synergistic collaborations w/ STPHARM
<i>Expansion of Pipeline</i>	<i>Collaborations</i>



■ CAR-NKT



- 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)

Oligo New drug API (45.2 Billion KRW) led to increase sales of 2020 earnings, 20 Billion KRW increase comparing to previous year (2019)

1. Earning Figures 2. Other Figures

▪ Earnings Summary (Consolidated)

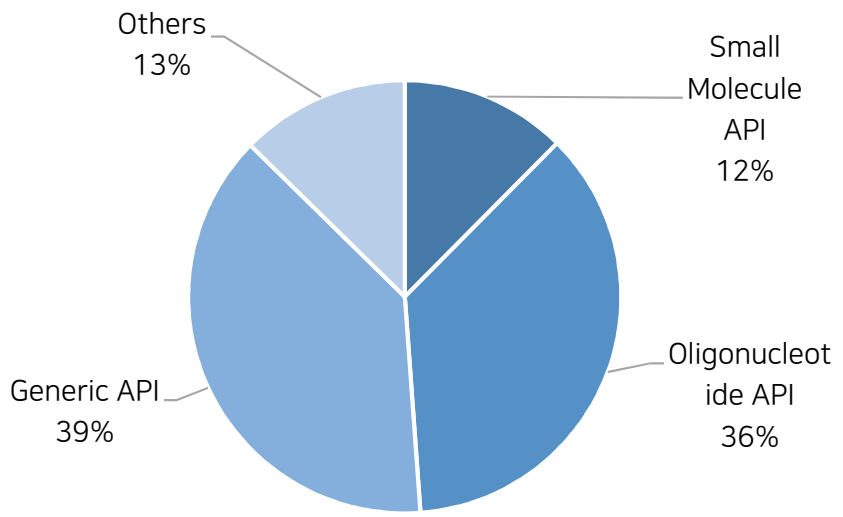
[Unit : Million KRW]

	2020	2019	2018
Revenue	124,109	93,257	97,738
COGS	104,123	94,885	94,959
Gross Profit	19,985	(1,628)	2,780
SG&A Expense	38,802	25,075	18,426
Operating Profit	(18,817)	(26,703)	(15,646)
Other Income	462	149	76
Other Expense	50	224	814
Financial Revenue	5,733	3,078	3,427
Financial Expense	4,154	1,272	433
Pre-tax Income	(16,824)	(24,973)	(13,391)
Tax Income (Expense)	3,670	6,444	4,123
Net Income	(13,154)	(18,529)	(9,268)
Owner of Parent attributable to net income	(12,147)	(18,529)	(9,268)
Non-controlling interests attributable to net income	(1,007)	-	-
Other comprehensive Income	504	(328)	(918)
Comprehensive Income	(12,650)	(18,856)	(10,186)

▪ Breakdown of Revenue

[Unit : Billion KRW]

Unit	2020	2019	2018	YoY
Small Molecule API	15.4	11.8	42.0	31.0%
Oligonucleotide API	45.2	25.2	14.3	78.8%
Generic API	47.7	45.7	36.7	4.4%
Others	15.7	10.5	4.8	50.7%
합계	124.2	93.3	97.7	33.1%



Issued Convertible Bond to invest the Oligo & mRNA Facility (110 Billion KRW). Improvement in Liquidity

1. Earning Figures

2. Other Figures

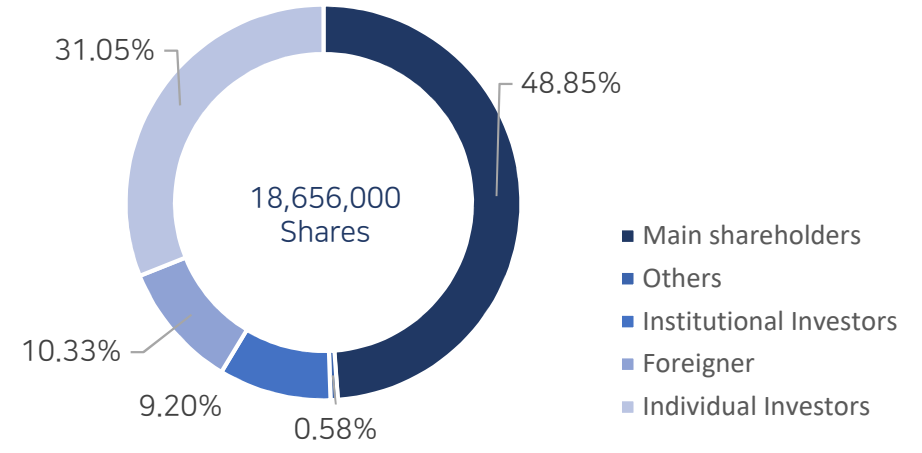
Balance sheet (Consolidated)

[Unit : Million KRW]

	2020	2019
Current Asset	235,613	144,152
Non-Current Asset	209,957	196,457
Total Asset	445,570	340,609
Current Liability	18,610	16,227
Non-Current Liability	130,206	21,173
Total Liability	148,817	37,400
Parent's Owners Equity	295,328	300,822
Capital stock	9,328	9,328
Retained Earnings	111,634	123,561
Shareholder's Equity	296,753	303,209

Shareholders Status

	Shares	Ratio	
Dong-A Socio Holdings	6,096,552	32.68%	Majority holder
Jung-Seok Kang	2,844,621	15.25%	Major holder of Holdings
Soo-suk culture foundation	171,600	0.92%	Foundation
Kyung-Jin Kim & 3 holders	15,325	0.05%	Board members
Total	9,121,864	48.85%	



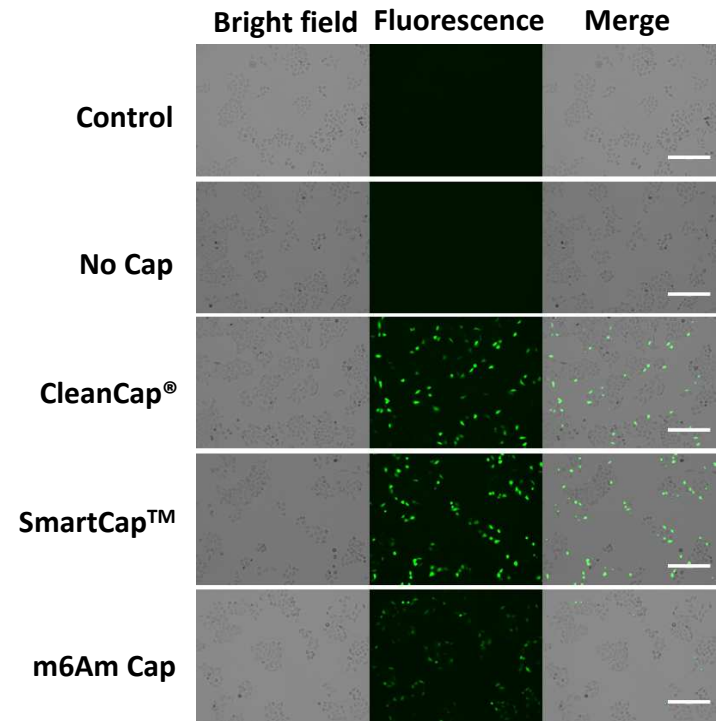
SmartCap™

- 5'-Capping enhances mRNA translation by inhibiting RNA decapping and improving resistance to enzymatic degradation
- **Strong IP position of ST Pharm's SmartCap™ using novel capping analogues**
- Promising results obtained from efficiency evaluation studies – immunofluorescence, Western blot and flow cytometry analysis
- Overall, SmartCap™ shows a better performance than **m6Am Cap** and comparable efficiency and expression level to **CleanCap®**
- Cost-effective leveraging ample nucleotide manufacturing experience
- Various different types of 5'-capping available for screening

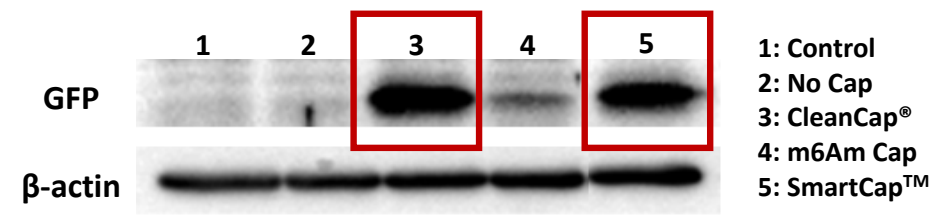
Summary

	m6Am Cap	CleanCap®	SmartCap™
EGFP expression level (compared to control)	1.7 fold	4.7 fold	4.0 fold
Flow cytometry analysis	5.4 %	17.0 %	16.0 %
Cost	1.5 X	1.5 X	1 X

A. Immunofluorescence assay (IFA)



B. Western blot analysis



❖ SmartCap™ library screening is available

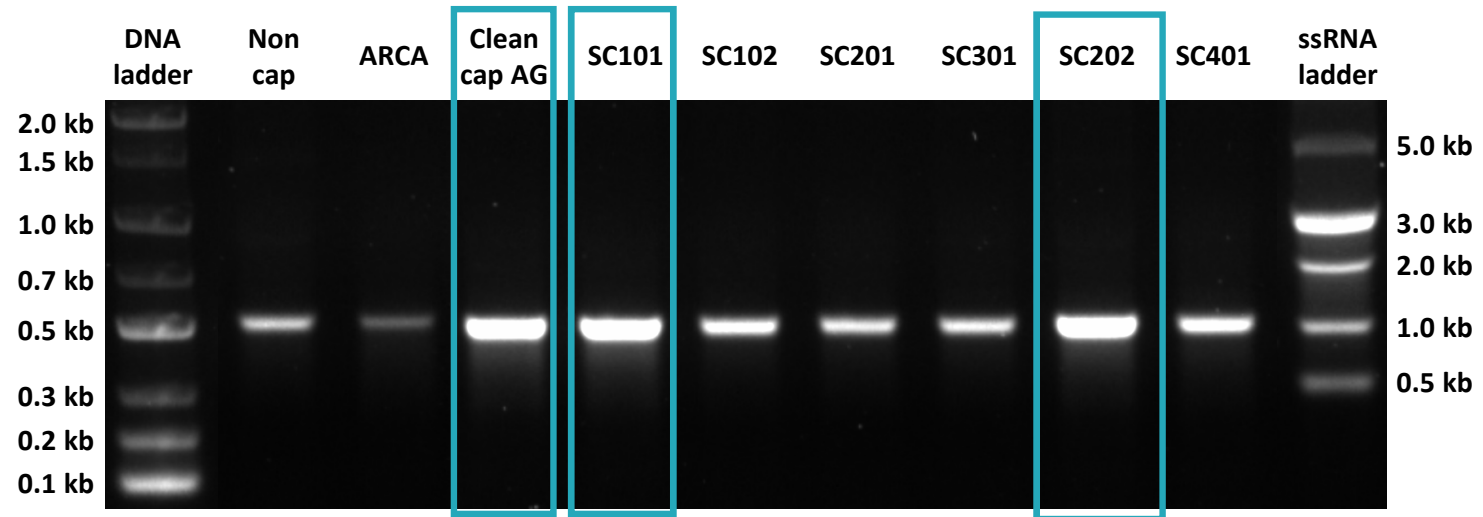
- To apply in various different targets including mRNA, siRNA, and gene-editing constructs
- To identify the best capping analogue with high capping efficiency
- To optimise customer's capping choice for their target sequence

❖ SmartCap SC101 and SC202 have shown a comparable mRNA capping efficiency to CleanCap AG

❖ SmartCap™ Library

SmartCap™
SC101
SC102
SC201
SC301
SC202
SC401

❖ Agarose gel electrophoresis



- 1% agarose gel, 10 uL sample loading

ST PHARM | IR BOOK

Thank You