IR Book | Feb. 2025

ST PHARM

Technology Driven Gene Therapy CDMO From Oligonucleotide to xRNA



Cautionary Statement regarding Forward-looking Statement

This presentation contains forward-looking statements from Dong-A Socio Group ("the Group") that include, but are not limited to, statements regarding our future financial performance, business strategies, market opportunities, product development, and operational plans. Words such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "project," "will," and similar expressions are intended to identify such forward-looking statements.

These forward-looking statements are based on our current expectations and beliefs concerning future developments and their potential effects on the Group. Such forward-looking statements are inherently subject to risks, uncertainties, and assumptions that could cause actual results to differ materially from those expressed in these forward-looking statements.

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Introduction







* Non-public subsidiary



Global **API CDMO** pioneering across RNA-based therapeutics

With certified GMP-grade Manufacturing capability across:

- Small Molecule
- Oligonucleotide
- mRNA
- sgRNA (CRISPR-CasX)



M DONG-A ST

Pharmaceutical company with focus on R&D of ethical drugs from NME to biosimilars

Major developments:

- IMULDOSA[™] [STELARA® BS] Approval (2024, FDA & EMA)
- DA-1726 Phase 1a [Obesity] (Ongoing, US)



Integrated CMO specializing in biosimilars and biologics

Songdo Site obtained FDA & EMA cGMP certification (PAI, 2024)

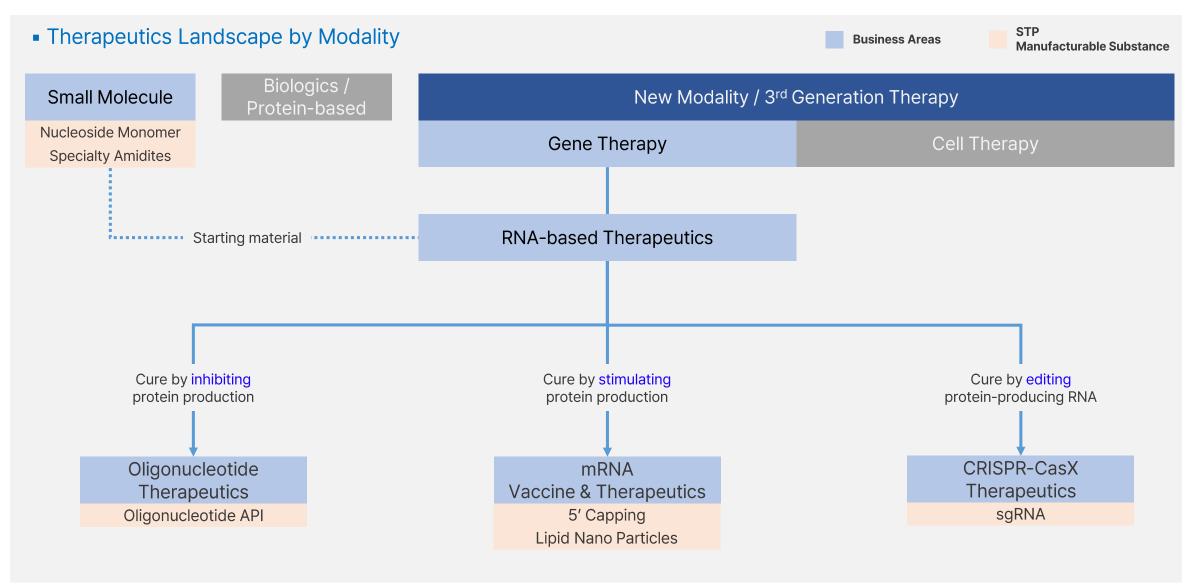
DS/DP Capacity:

- [DS] USP & DSP: 9,000L
- [DP] Fill & Finish: 10,800 syr/h

Overview



Introduction to Core Business Areas

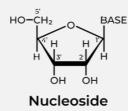


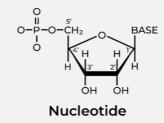
Overview



History & CDMO Records

Nucleosides API





Oligonucleotide API



Oligonucleotide (Single-strand)

xRNA CDMO Platform



CDMO specializing in small-molecule nucleoside APIs for anti-viral medications

API Supplier of

GSK Thymidine GSK Zidovudine Novartis Telbivudine Gilead Sofosbuvir

Integrated value chain from nucleosides to phosphoramidites

2018

First commercial-scale Oligo Plant

2022

NAI grade from US FDA PAI Inspection

2023

- US FDA Inspection for Banwol Site
- 2nd commercial-scale plant (under construction)

2024

3rd Commercialized Oligo CDMO received US FDA Approval

2023

Commercial-scale mRNA production facility

2024

- Application of STLNP® Patent(PCT)
- Supply Agreement with Quantoom Bio.
- Completion of in-house developed 5'-Capping (SmartCap®)

2025

 mRNA Partnership with Evonik AG (SmartCap®)

Market

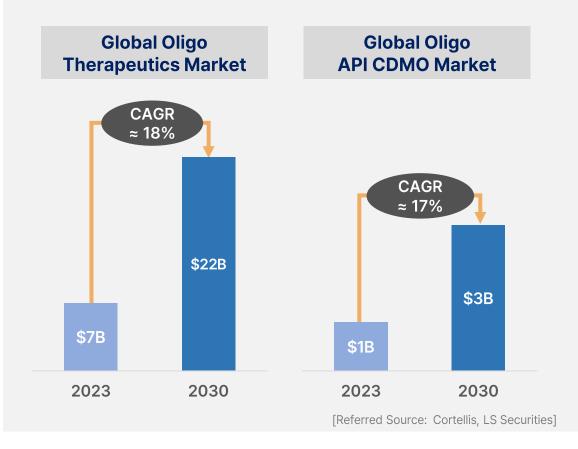


Oligonucleotide Therapeutics & CDMO Market

Oligonucleotide Market Growth Forecast

Therapeutics market size to achieve **double-digit growth** through 2030, with CDMO market reflecting ≈15% of downstream market

R&D landscape expanding to target diseases with larger population → from rare & hereditary to chronic diseases (CVD, metabolic, etc.)



[Clinical experiments undergoing fast-paced advancements] (Pipeline Counts, includes ASO and RNAi) ~ 12. 2022 ~ 11. 2024 137 68 41 23 21 16 ~ Phase 1 ~ Phase 2 ~ Phase 3 / NDA Approved

[Source: Synapse]



Business Overview

Business



Production Facility (GMP)

Overall Capacity

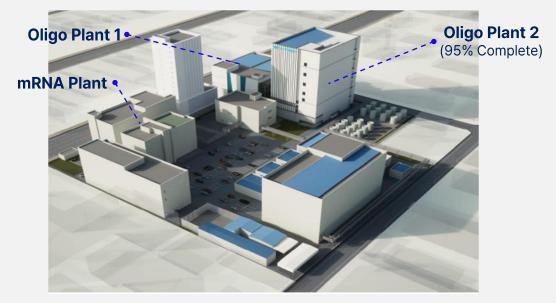
Fooility	Chemical Plant	Oligo Plant	mRNA Plant
Facility	SM, Generic, Monomer	Oligonucleotide API	mRNA, Lipid Nano Particles
Equipment Status	96 (Reactors)	4 (Lines)*	-
Total Capacity	376,250 L	6.4 mole (≈ 2.2T)**	Max. 100M Dose/Year

^{*} No. of Lines based on installed synthesizers

View of Siwha Campus (Chemical)



■ View of Banwol Campus (RNA TX API)



^{** 1} mole ≈ 167kg ~ 500kg

Business



CDMO Business – New Drug API

Major CDMO Projects

# Client		Indication / Townsh Discoss	Stage			
#	Client	Indication / Target Disease	P1	P2	Р3	Approved
Olig	onucleotic	de API				
1	1 Client A	Hyperlipidemia				
•	Client A	Atherosclerotic(AS) CVD	→ Indication expansion			
2	Client B	Spinal Muscular Atrophy (SMA)				
3	Client C	Myelodysplastic Syndrome (MDS)				
3	Client C	Myelofibrosis (MF)	→ Ind			
4	Client D	Familial Chylomicronaemia Synd.				
4	Client D	Severe Hyper-triglyceridema	→ Ind	ication exp	ansion	
5	Client D	Hereditary Angioedema				
6	Client A	Atherosclerosis				
7	Client F	IgA Nephropathy				
8	Client E	Chronic Hepatitis B				
9	Client F	Chronic Hepatitis B				
10	Client F	Huntington's Disease				
Small Molecule API						
11	Client G	Not disclosed				
12	Client H	Mitochondrial Dysfunction				

Capacity Expansion Schedule (Oligo Plant)

Eggility	Operation starting by 25.Q4	2028 ~
Facility	Plant 2	Plant 2 Expansion
Total Lines	7	~ 10
Total Capacity	8 mole	TBD
CAPEX (KRW)	110 Billion	~ 40 Billion

• '23 ~ '24 Oligo CDMO Project Backlog Status (as of 3Q.24)

Project	Contract Duration	C	Contract Size	ı	Backlog	Progress
Llyporlinidomio	23.03 ~ 24.12	\$	48.5 M	\$	18.7 M	62%
Hyperlipidemia	24.08 ~ 25.12	\$	63.3 M	\$	63.3 M	0%
SMA	23.03 ~ 24.05	\$	9.0 M	\$	_	100%
	23.02 ~ 24.06	\$	8.6 M	\$	_	100%
MDS	23.05 ~ 24.12	\$	27.3 M	\$	12.0 M	56%
IVID2	23.06 ~ 24.12	\$	8.6 M	\$	-	100%
	24.08 ~ 25.12	\$	35.7 M	\$	35.7 M	0%
FCS	24.06 ~ 24.12	\$	4.5 M	\$	4.5 M	0%
Others	_	\$	49.8 M	\$	24.1 M	52%
Total			255.2 M	\$	158.2 M	38%

Business



CDMO Business - mRNA Platform

ST Pharm's In-house Platform Technologies

SmartCap®

- Registered patent in Korea
- Ongoing PCT International Patent Publication
- Over 30 capping analogues → highly customizable
- Efficacy & Safety data through STP-2104 clinical trial (P1)

UTR Coding Sequence UTR Poly(A)n Capping (SmartCap®)

Supply Agreements & Partnerships:

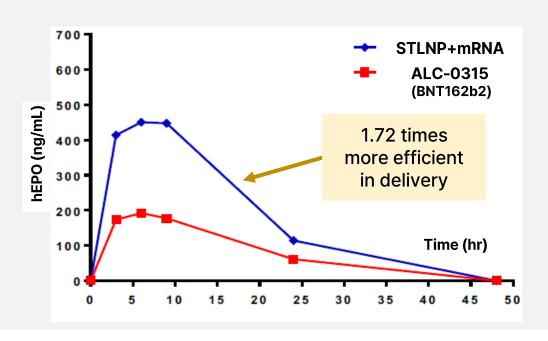




Jan. 2025

STLNP®

- Ongoing PCT International Patent Publication
- Delivery efficacy data observed from nonclinical study





Technology & Pipeline

Technology •



Enzymatic Ligation for Oligonucleotide CDMO

Development of Enzymatic Ligation approach to revolutionize API production at scale...

Our Approach

- 1) Synthesize monomers into shortmers instead of phosphoramidites as individual building blocks
- 2) Synthesize shortmers into full-length oligo APIs through enzymatic ligation
- * Ongoing joint research with global pharmaceuticals/clients for commercialization of technology

Why it matters

- Improves scalability & lowers production cost
- Eco-friendly, by using non-chemical organic solvents (ex. water)
- Allow efficient synthesis of longer-length oligomers/oligonucleotides

[Solid Phase OS] [Enzymatic Ligation OS] **Oligonucleotide Synthesis** (ASO) Oxidation Deblocking Repeat x Times [Source: Twist Bioscience]

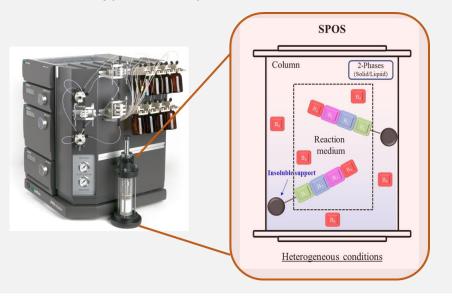
Technology POS for Shortmer CDMO



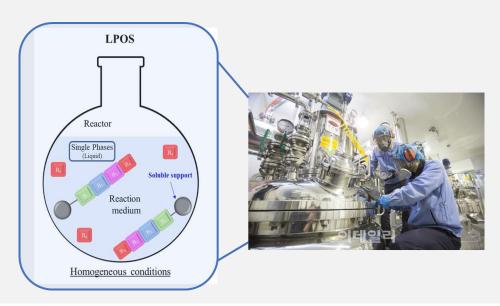
- combined with Liquid Phase Synthesis for mass production of shortmers
 - Our Approach
 - 1) Mass produce shortmers through Small Molecule-like liquid phase synthesis
 - 2) Synthesize LPOS-made shortmers into full oligo APIs through ligation
 - * Acquired global (excl. Japan) license of LPOS-enabling liquid resin from Fujimoto Chemical

Why it matters

- Greatly enlarges batch size compared to SPOS-made shortmers (x10 of current SPOS batch size)
- Improve synthesis efficiency and shorten production lead time, resulting in cost optimization
- Eco-friendly; LPOS require less chemical solvents than SPOS











sgRNA Chemical Synthesis for CRISPR-Cas CDMO Service

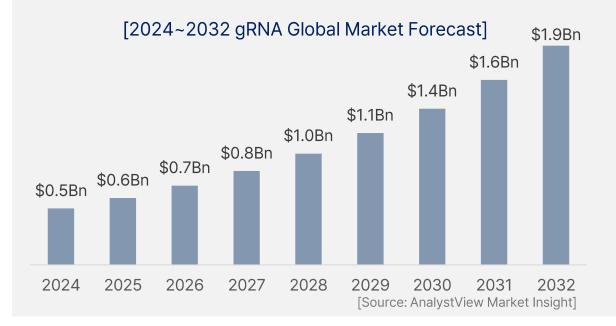
sgRNA synthesis in response to CRISPR-Cas demands

Successful manufacturing of 100-mer sgRNA

- Backed by +20 years of expertise in oligo./nucleotide synthesis and development of analytical methods
- Full in-house production capability

Ongoing developments and production augmentation

- 130-mer sgRNA development work-in-progress
- On schedule for installing dedicated line during 1Q.2025



[100-mer sgRNA Purification Results]

As of Oct. 2024

Length	Modification	Crude (Pre-Purification)	Post Purification
100 mer	2'-OH	7~17 %	79~87%*

^{*} Major competitor Target purification ≥ 80% (100-mer)

[Production Facility Status (GMP)]

Status	Line	Capability
Installed	R&D Lab Line* (non-GMP)	50 µmol ~ 1.2 mmol
Installed	Small-scale Line*	1.2~20 mmol
Planned	Small-scale Line [sgRNA-dedicated]	1.2 mmol scale

^{*} Currently utilizing two installed lines for both oligonucleotide & sgRNA synthesis

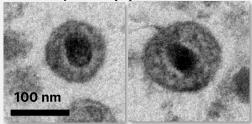
Pipeline



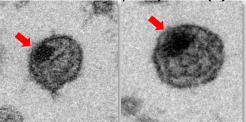
STP0404 - ALLINI Mechanism (New Mechanism)

STP0404 Mechanism of Action

Before Injection (A)



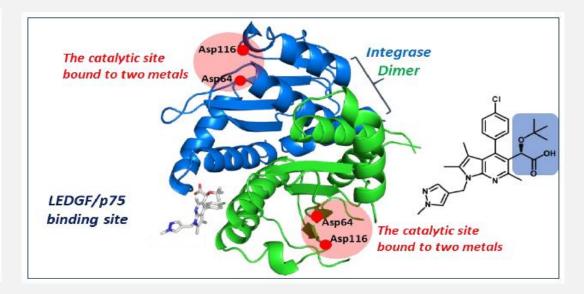
After STP0404 0.2µM Injection **(B)**



TEM study in Emory Univ.

Infectious HIV-1 without inhibitor without inhibitor without inhibitor Integrase inhibitor (ALLINI) integrase viral RNA nucleocapsid capsid matrix Kessl et al., Cell, 2016, 166, 1257

STP0404 X-ray Structure



- New mechanism ALLINI (Allosteric integrase inhibitor) founded by Prof. M. Kvaratskhelia (Univ. of Colorado) in 2016
- Integrase delivers HIV virus's RNA to host cell, inducing virion state (infection of host cell & capsid protection) (A)
- ALLINI inhibits delivery / merge of integrase with virus's RNA, causing mislocalization of HIV's RNA (B)
- STP0404 pulls the HIV virus's RNA outside the virus-protecting capsid, allowing the formation of non-infectious HIV-1 (B)
- New MOA for HIV-cure as "maturation inhibitor" "Divide and Conquer", not 'Shock & Kill' or 'Block & Lock"
- Identification of ALLINI mechanism supported by US NIH grants in 2018. Collaboration with Emory University & University of Colorado Boulder



Dong-AST

Pipeline



IMULDOSA: Stelara® Biosimilar

Developer Dong-A ST & Meiji Seika Pharma

ODONG-A ST Meiji (INTAS) accord

• License Agreement Accord BioPharma Inc. (US) / Accord Healthcare (EU)

• Manufacturing Exclusive production from dedicated lines from STgen Bio

• Formulation PFS (Pre-Filled Syringe): 45mg/0.5mL & 90mg/1.0mL (Subcutaneous administration)

Vial: 130mg/26mL (Intravenous administration)

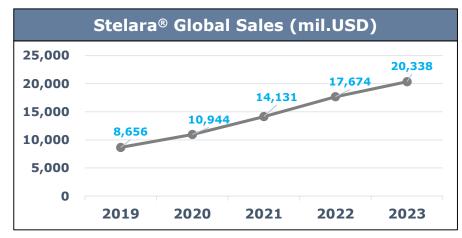
Indication
 Plaque psoriasis, psoriatic arthritis, Crohn's disease, ulcerative colitis

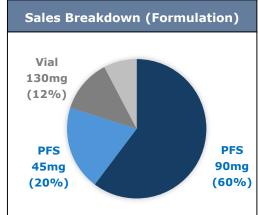
• Regulatory Actions Oct. 24 US FDA Approval (Sales after May. 25), Dec. 24 EU EMA Approval (Sales after Jan. 25)



Stelara® Market Size

Global Market Size: \$2 Billion (US accounting for 77%) in 2023*





Sales Breakdown by Geography			
	Country	2023 sales	
1	US	\$15,613,485,771	
2	GERMANY	\$873,639,172	
3	CANADA	\$663,584,550	
4	SPAIN	\$503,833,653	
5	JAPAN	\$431,487,690	
6	UK	\$379,793,159	
7	FRANCE	\$358,543,753	
8	ITALY	\$237,373,247	
9	AUSTRALIA	\$236,356,408	
10	PUERTO RICO	\$99,112,125	

18

* Source: IQVIA global data

Pipeline



DA-1726: Anti-Obesity (GLP1/GCG dual agonist)

Indication Obesity, MASH

MOA GLP1R / GCGR Dual Agonist

Market Size Global \$2.8 Billion (2022) → \$16.7 Billion (2028) ¹⁾

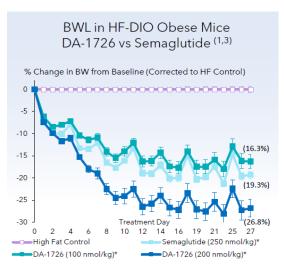
Status Reported positive safety results from Phase 1 [Part 1] (Oct. 24), Ongoing Phase 1 [Part 2] (Expected release 1Q25)

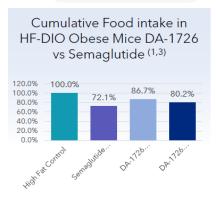
Scheduled for Phase 1 [Part 3] during 2Q25 (24-week, expected 12-week interim results in 1H26)

Highlight Reported superior weight-loss despite higher food intake compared to Wegovy and Zepbound (Pre-clinical results)

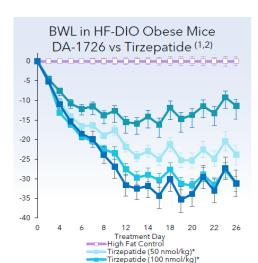
Efficacy Results (Pre-clinical)

vs. Wegovy

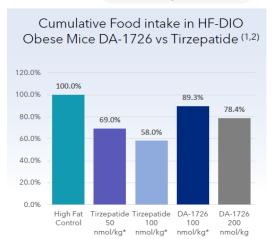




Weight loss observed from DA-1726 is attributed to reduced food intake via GLP1R and increased energy expenditure via the GCGR



DA-1726 (100 nmol/kg)* DA-1726 (200 nmol/kg)*



vs. Zepbound

Thank You

ST PHARM

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