IR Book | Nov. 2024

ST PHARM

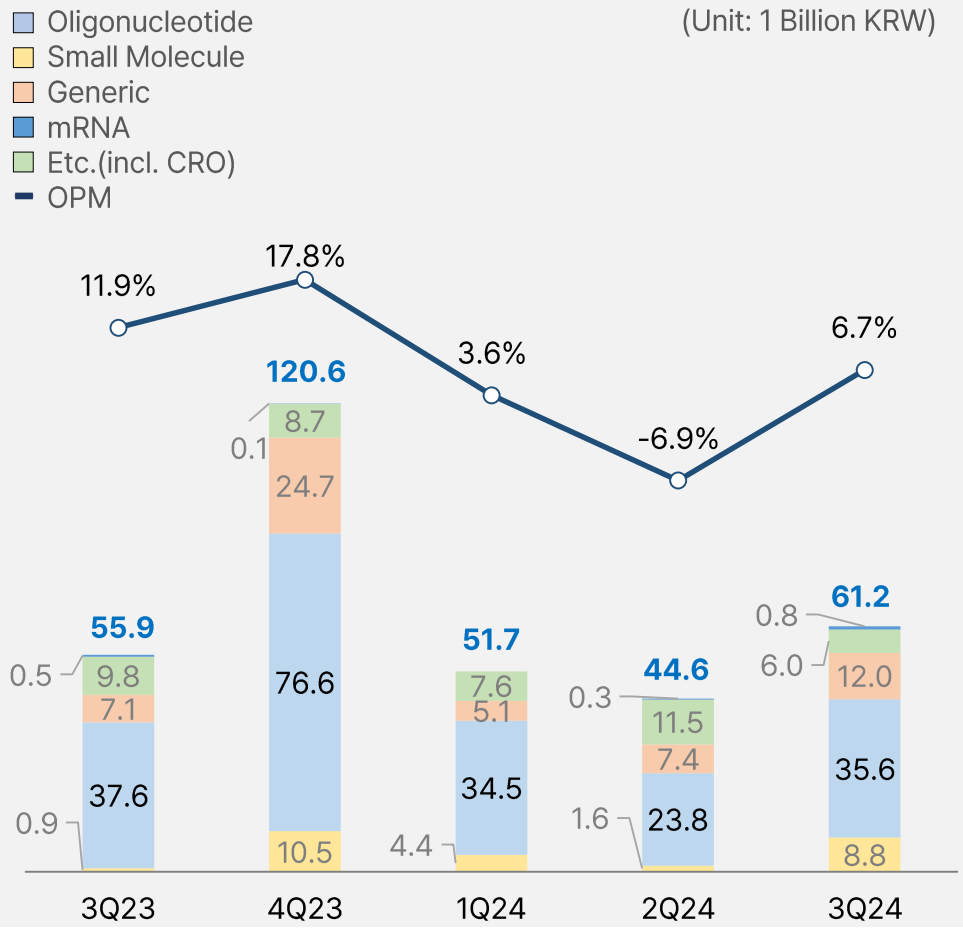
Technology Driven Gene Therapy CDMO
From Oligonucleotide to xRNA

Earning Result

2024 3Q Financial Statement (Preliminary)

▪ Consolidated Financial Results

5-Quarterly Performance trend



▪ Financial Statement

Revenue ₩ 61.2 Bn, Operating Profit ₩ 4.1 Bn, Net Profit ₩ 9.6 Bn

※ Separate Results: Revenue ₩ 57.2B, Operating Profit ₩ 9.8B, Net Income ₩ 15.9B

1) Added product orders from commercialized projects were driver of sales growth
2) CRO losses caused by slower-than-expected nonclinical study demands and adjustments as a result of change in accounting standard

Accounts (Unit: 1 Billion KRW)	2023	'23.3Q	'24.3Q	YoY
Revenue	**285.0**	**55.9**	**61.2**	**+9.4%**
Cost of Goods Sold	172.9	31.6	40.7	+28.9%
Gross Profit	112.1	24.3	20.5	-15.9%
SG & A Expenses	78.6	17.7	16.4	-7.4%
R&D Expenses	30.4	6.6	6.1	-8.3%
Operating Profit	**33.5**	**6.7**	**4.1**	**-38.5%**
Net Profit	**17.5**	**3.4**	**9.6**	**+185.1%**
Gross Profit Margin	*39.3%*	*43.5%*	*33.4%*	*-10.1%p*
Operating Profit Margin	*11.8%*	*11.9%*	*6.7%*	*-5.2%p*
EBITDA Margin	*16.3%*	*16.8%*	*30.7%*	*+14.0%p*

Earning Result

2024 3Q Financial Results by Business

▪ Business Breakdown

(Unit: 1 Billion KRW)

Sector		'23.3Q	'23.4Q	'24.1Q	'24.2Q	'24.3Q	YoY
Oligo. CDMO	**Subtotal** (% of Total Revenue.)	**37.6** (67.2%)	**76.6** (63.5%)	**34.5** (66.8%)	**23.8** (53.3%)	**35.6** (58.1%)	**-5.4%**
	Commercial	8.4	52.9	15.2	13.1	29.6	252.1%
	Clinical	29.2	23.7	19.3	10.7	5.9	-79.7%
Small Molecule API (SMA)		0.9	10.5	4.4	1.6	8.8	900.9%
mRNA		0.5	0.1	0.0	0.3	0.8	50.3%
Generic API (GA)		7.1	24.7	5.1	7.4	12.0	70.5%
Others		0.7	0.4	0.0	0.5	0.0	-98.6%
Separate Revenue		**46.7**	**112.3**	**44.1**	**33.6**	**57.2**	**22.4%**
Subsidiaries (CRO)		9.2	8.3	7.6	10.9	4.0	-56.7%
Consolidated Revenue		**55.9**	**120.6**	**51.7**	**44.6**	**61.2**	**9.4%**

▪ Comments

Oligo. API CDMO business sales declined 5.4% YoY
Commercialized project sales increased 252.1% YoY

- Factors of CRO Loss
  Slow recovery of nonclinical study demand from biotech clients led to lower-than-expected sales growth

  Change in accounting standard led to adjustments in past-recognized revenue from clients' contract sales

  Anticipate majority of adjustment impact in 3Q, minor impact in 4Q
  (non-recurring item recognized for 2H.24)

- Anticipated Events and Outlook
  1 anticipated approval of Oligo project within 2H.24

  1 Oligo and 1 SM project anticipated for approval within 2025

PART 01

Introduction

Overview

Introduction

Summary

(By end of 2023)

Establishment	1983
Equity	386.9 Billion KRW
Employees	669
Revenue	285 Billion KRW (Overseas 82%, Domestic 18%)
Shareholders	Affiliated / Affiliated Persons hold 45.6%

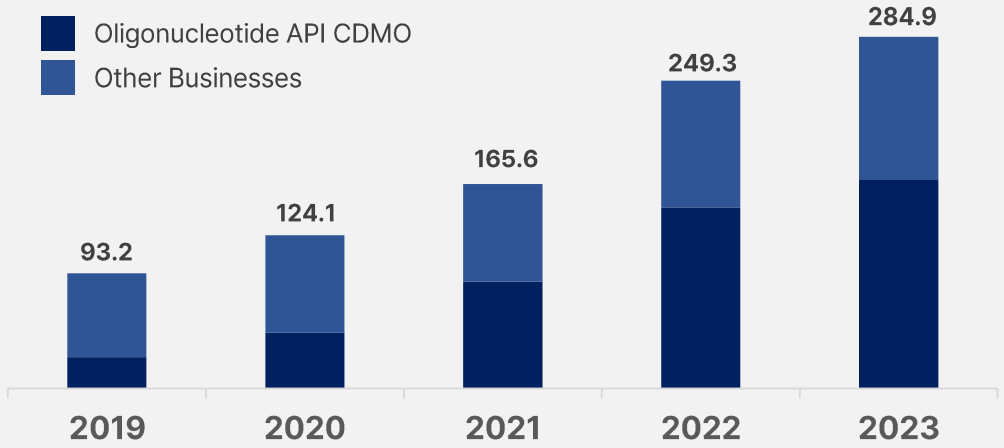
Major global player in Oligonucleotide API CDMO with capability across **entire Oligo. API value chain**

Coverage **from Small Molecule to xRNA APIs**

Successful inspections from global regulatory agencies

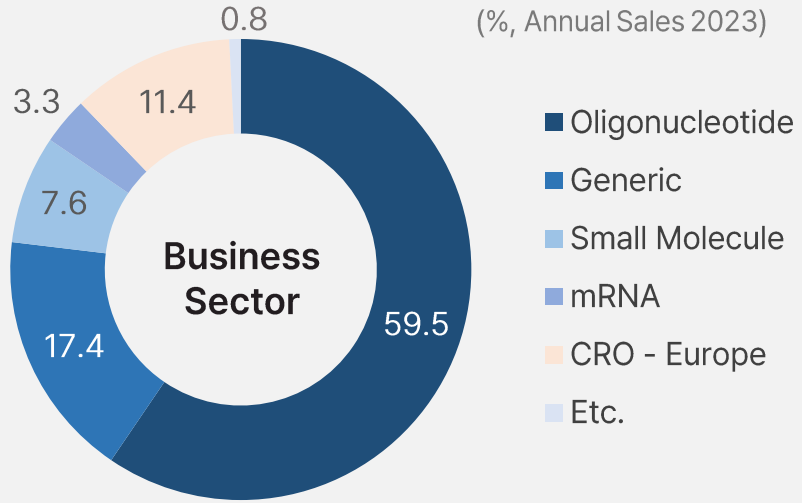
Solid **records in both CDO and CMO** areas

Consolidated Annual Revenue (Unit: 1 Billion KRW)



Revenue Breakdown

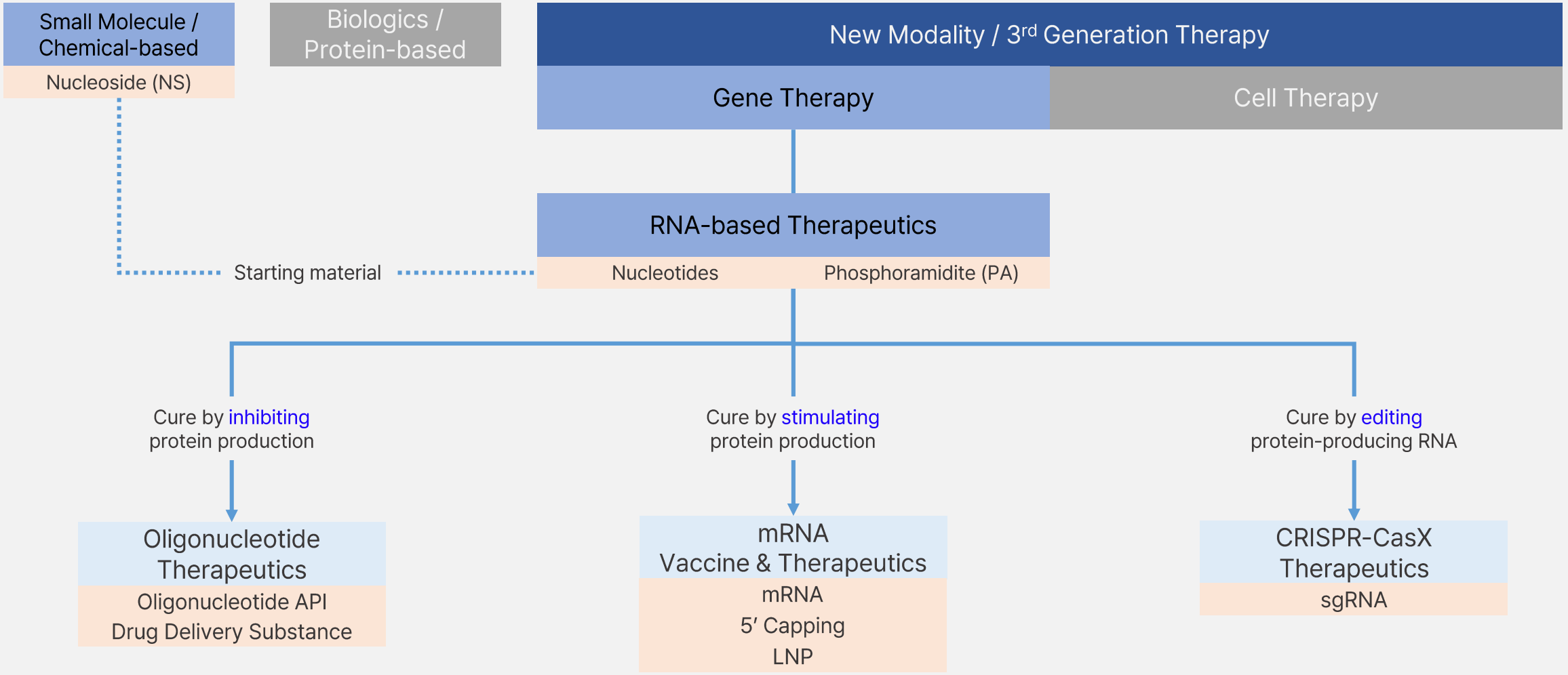
(%, Annual Sales 2023)



Overview

Landscape of Therapeutics based on Modality

- Therapeutics Landscape

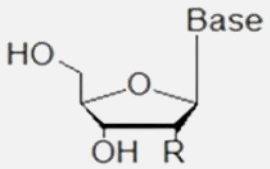


Overview

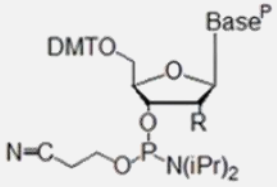
History & CDMO Records

Nucleosides API

Nucleoside



Phosphoramidite



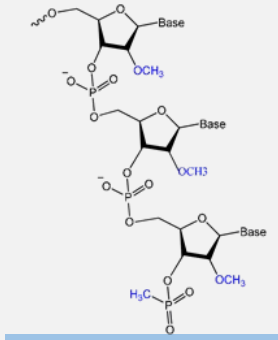
CDMO specializing in small-molecule nucleoside APIs for anti-viral medications

API Supplier of

GSK Thymidine
GSK Zidovudine
Novartis Telbivudine
Gilead Sofosbuvir

Integrated supply chain from nucleosides to phosphoramidites

Oligonucleotide API



Small-interfering

Anti-Sense

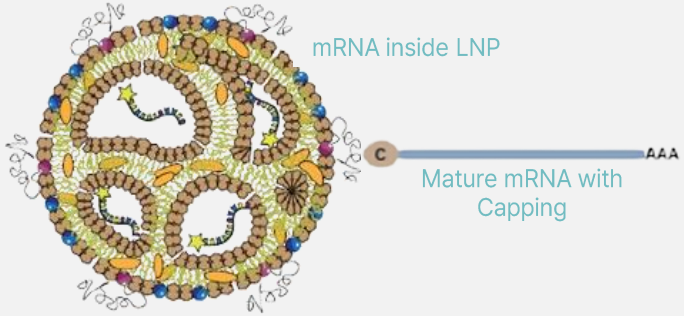
2018
- First commercial-scale Oligo. production facility

2022
- NAI grade from US FDA PAI Inspection

2023
- US FDA Inspection for Banwol Site
- 2nd commercial-scale plant (under construction)

2024
- 3rd Commercial-scale project with US FDA's approval of MDS medication

xRNA CDMO Platform



2022
- First delivery of LNP lipid

2023
- Commercial-scale mRNA production facility

2024
- Application of STLNP® Patent(PCT)
- Completion of STP2104 Clinical Trial(P1)
- Supply Agreement with Quantoom Bio.

PART 02

Business Overview

Business

Production Facility (GMP)

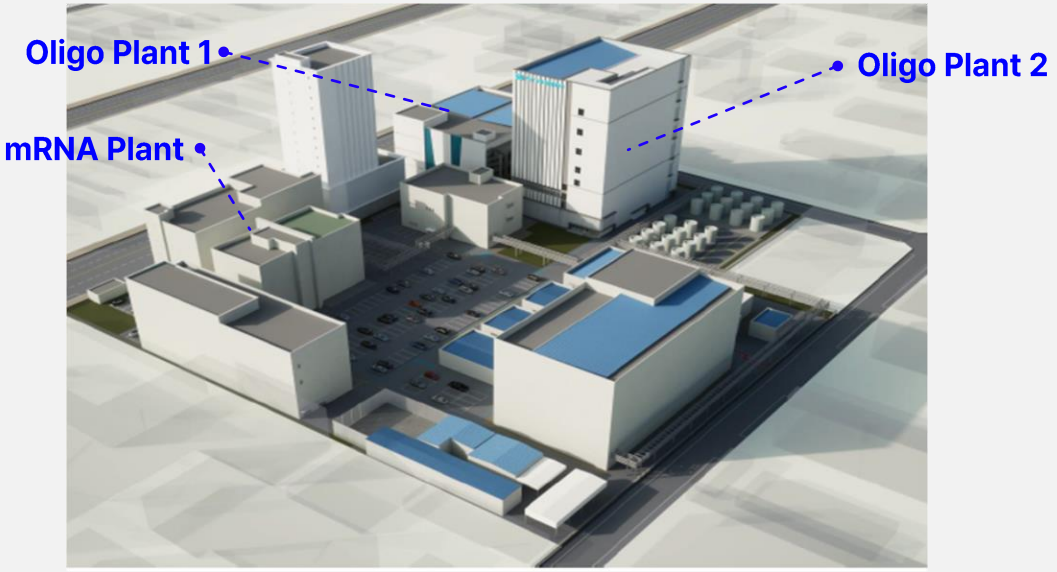
▪ Overall Capacity

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

* No. of Lines based on installed synthesizers
** 1 mole ≈ 167kg ~ 500kg

▪ View of Siwha Campus

▪ View of Banwol Campus



Business

CDMO Business – Oligonucleotide API

▪ Major Projects Under Management

#	Client	Indication	Stage			
			P1	P2	P3	NDA
Oligonucleotide API						
1	Client A	Hyperlipidemia				
		Atherosclerotic(AS) CVD	↳ Indication expansion			
2	Client B	Spinal Muscular Atrophy				
3	Client C	Myelodysplastic Syndrome				
		Myelofibrosis (MF)	↳ Indication expansion			
4	Client D	FCS* (CVD)				
		Severe Hypertriglyceridema	↳ Indication expansion			
5	Client D	Hereditary Angioedema				
6	Client A	Atherosclerosis				
7	Client E	Chronic Hepatitis B				
8	Client F	IgA Nephropathy				
9	Client E	Chronic Hepatitis B				
10	Client F	Chronic Hepatitis B				
Small Molecule API						
1	Client G	Not disclosed				
2	Client H	Mitochondrial Dysfunction				

* FCS: Familial chylomicronaemia syndrome

▪ Capacity Expansion Schedule (Oligo Plant)

Facility	2025.Q3	2026 ~
	Plant 2	Plant 2 Expansion
Maximum Lines*	7	10
Total Capacity**	~ 8 mole	~ 13 mole
CAPEX (KRW)	110 Billion	40 Billion

* No. of Lines based on installed synthesizers
** 1 mole ≈ 167kg ~ 500kg

▪ Potential new projects under negotiation

Client	Target Disease	Client	Target Disease
A	Hypertension	C	Skin Cancer
A	Huntington	D	CNS
A	Alzheimer's Disease	E	Resistant Hypertension
B	Alpha 1-Antitrypsin Deficiency	F	Myotonic Dystrophy Type 1
B	Not Disclosed	G	Epilepsy

* Unrelated with client symbols from "Major Projects Under Management"

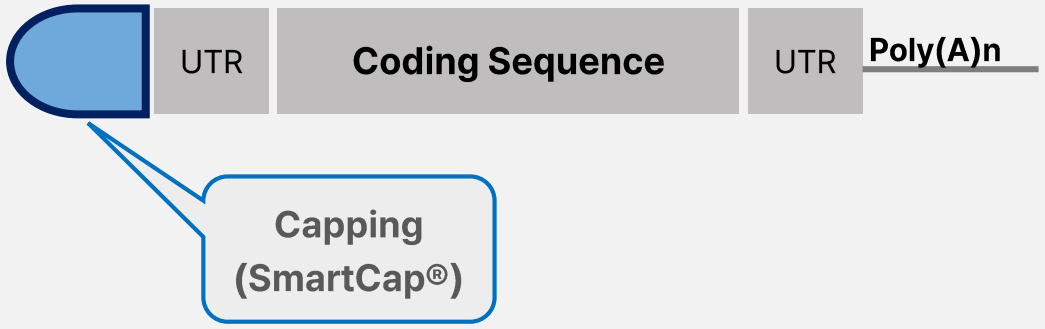
Business

CDMO Business – mRNA Platform

- ST Pharm's In-house Platform Technologies

SmartCap® (Stability)

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

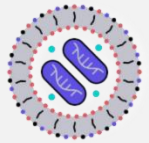


Official Supply Agreement of SmartCap® with:

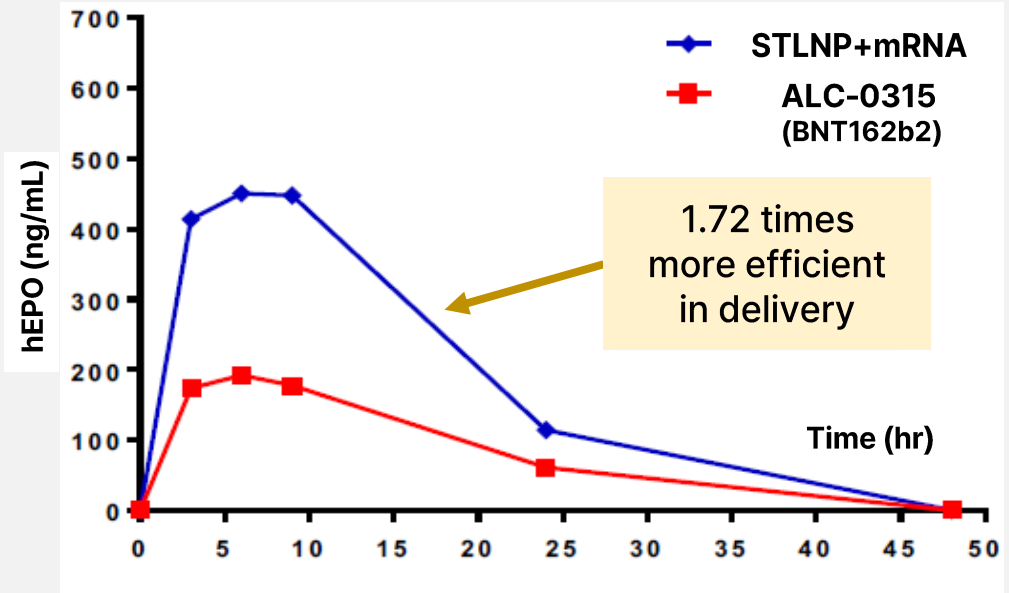
Quantoom Biosciences

Aug. 20, 2024

STLNP® (Delivery)



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



PART 03

Technology & Pipeline

Technology

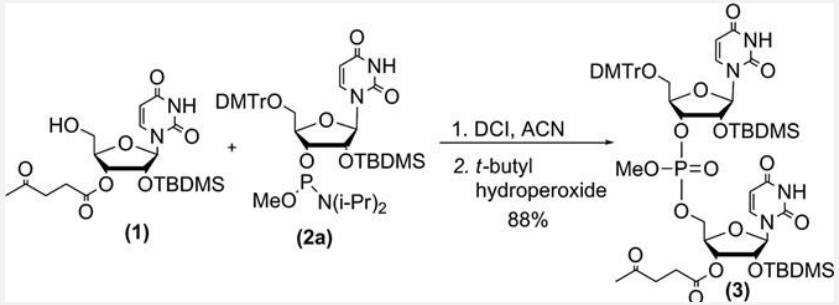
Dimer Block RNA Synthesis for Oligonucleotide CDMO

- Synthesis of siRNA Using Dimer Blocks

  Synthesis of block-PA(condensed di-nucleotide PA) on solid support, instead of single-monomer PA

  Allow faster reactions & higher yield, skipping several synthesis steps

  ↳ suitable for **large scale API production** with established production protocol



Example of Dimer Block Synthesis

- Comparison between Monomeric Synthesis with Block Synthesis

Synthesis of oligonucleotides via monomer and block coupling

Entry	Oligomer 5′-to-3′	Amidite	Concd (M)	# of couplings	Time (min)	Coupling efficiency (%)	Yield[a] (%)	
I	$(rU)_{18}dT$	rU (**2a**)	0.10	18	10	98.5	76.5	
II	$(rU)_{18}dT$	rU (**2a**)	0.15	18	20	98.7	80.1	→ Monomer
III	$(rU)_{18}dT$	rUU (**9a**)	0.10	9	10	97.2	77.8	
IV	$(rU)_{18}dT$	rUU (**9a**)	0.15	9	20	98.3	85.9	→ Dimer Block
V	$(rU)_{18}dT$	rUUU (**14a**)	0.10	6	10	86.5	41.8	
VI	$(rAAUU)_4dTdT$	rUUU (**14a**)	0.15	6	20	97.2	84.7	
VII	$(rAAUU)_4dTdT$	rU (**2a**), rA (**2b**)	0.15	16	20	98.0	72.5	
VIII	$(rAAUU)_4dTdT$	rUU (**9a**), rAA (**9b**)	0.15	8	20	98.5	88.8	

Overall, block synthesis yielded 4~5% more products with similar efficiency compared to monomeric synthesis

[Source : "RNA synthesis via dimer and trimer phosphoramidite block coupling", Tetrahedron Letters]

Technology

Liquid Phase Synthesis for Oligonucleotide CDMO

- Development of Novel Oligo Synthesis Method by combining Liquid Phase and Enzymatic Oligo Synthesis

Potential Advantage of LPOS

- Larger batch size compared to SPOS
- Similar methodology with traditional chemical synthesis process

* Acquired global(ex Japan) license of LPOS-enabling liquid resin from Fujimoto Chemical

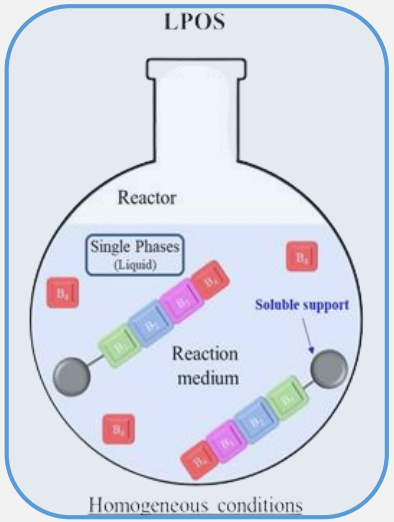
Potential Advantage Enzymatic OS

- Relatively easier purification process with higher synthesis efficiency under moderate(room) temperature condition

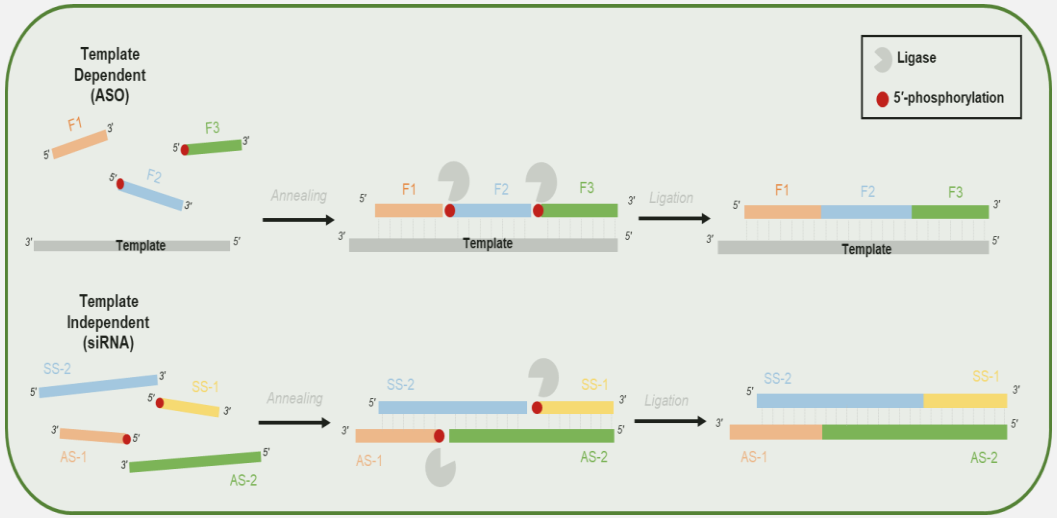
* Ongoing joint research with global pharmaceuticals for commercialization

[Solid Phase OS]
(Equipment)

[Liquid Phase OS]



[Enzymatic OS]

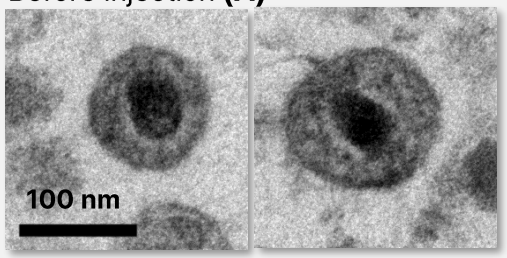


Pipeline

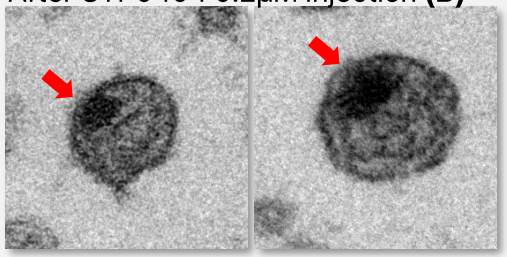
STP0404 - ALLINI Mechanism (New Mechanism)

▪ STP0404 Mechanism of Action

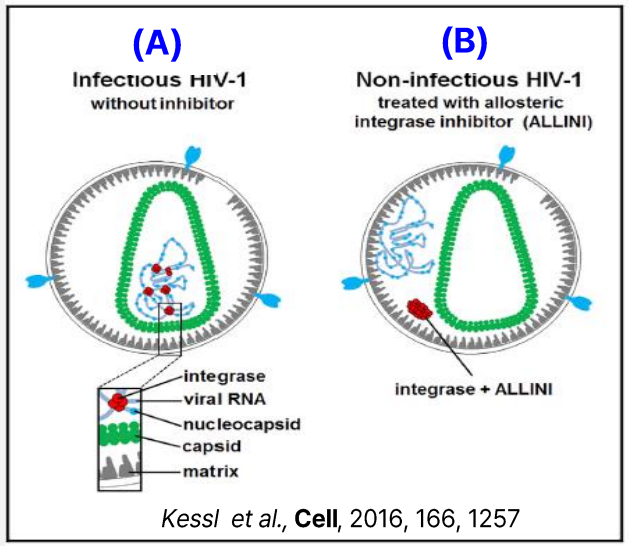
Before Injection **(A)**



After STP0404 0.2μM Injection **(B)**

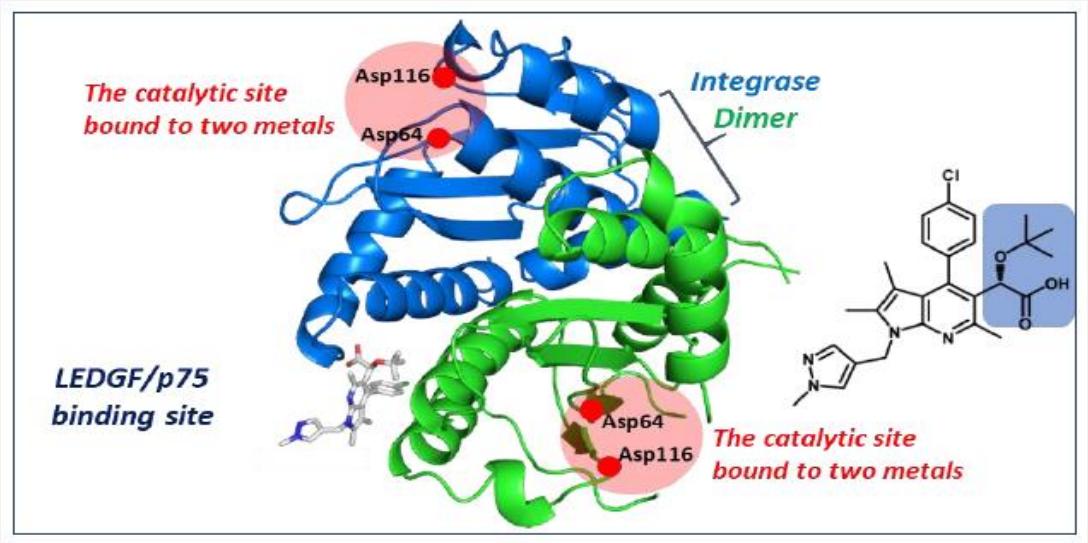


TEM study in Emory Univ.



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

Thank You

ST PHARM

Technology-Driven Gene therapy CDMO
From Oligonucleotide to xRNA

PART 04

Appendix

Market

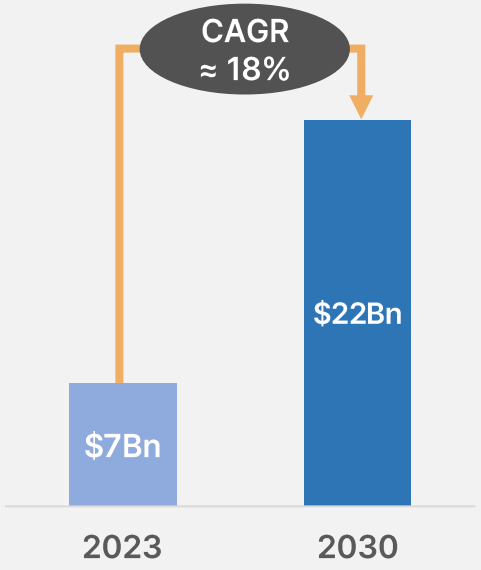
Oligonucleotide Therapeutics & CDMO Market

▪ Oligonucleotide Market Growth Forecast

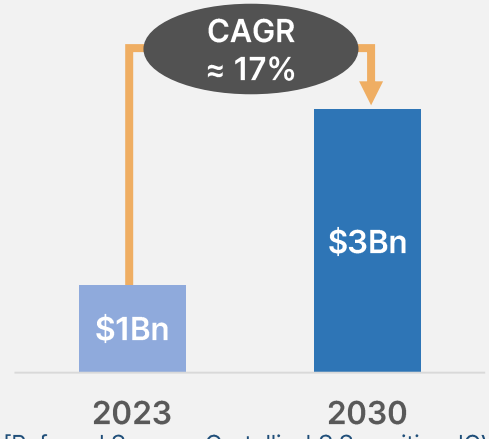
Global Market size to achieve **double-digit growth** through 2030

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

Global Oligo Therapeutics Market

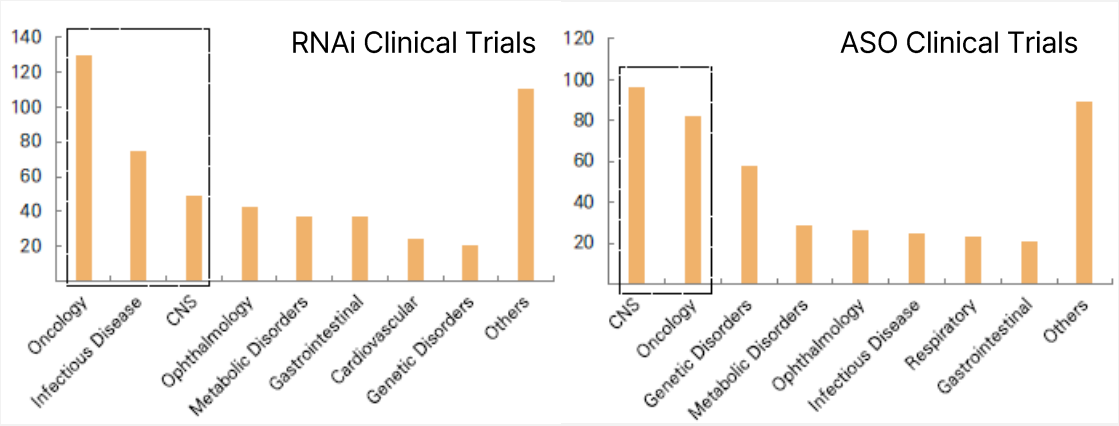


Global Oligo CDMO Market



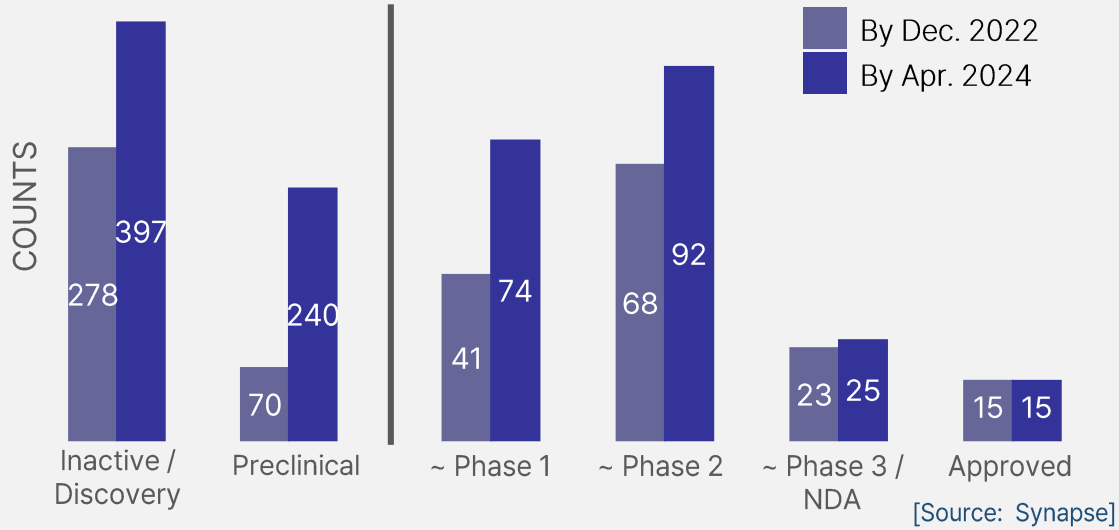
[Referred Source: Cortellis, LS Securities, IQVIA]

▪ Therapies targeting Diseases with Larger Patients Population



[Source: Mirae Asset Securities, Globaldata(2022)]

▪ Pipeline Development Landscape (ASO + RNAi)



[Source: Synapse]