43rd Annual J.P. Morgan Healthcare Conference

Axcelead as Global Healthcare Platform Company

Jan. 16, 2025

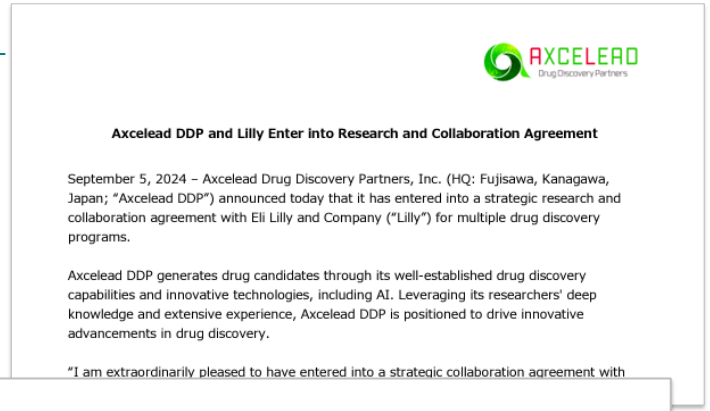
Axcelead, Inc., Board Director, Co-CEO and CTO

Yoshinori Ikeura

Our Achievements in 2024

Expanded partnership IDD model with milestones

- Research and Collaboration agreement with Lilly in August
- Master Service Agreement for Drug Discovery Projects with Acadia in September



AXCELEAD Drug Discovery Partners

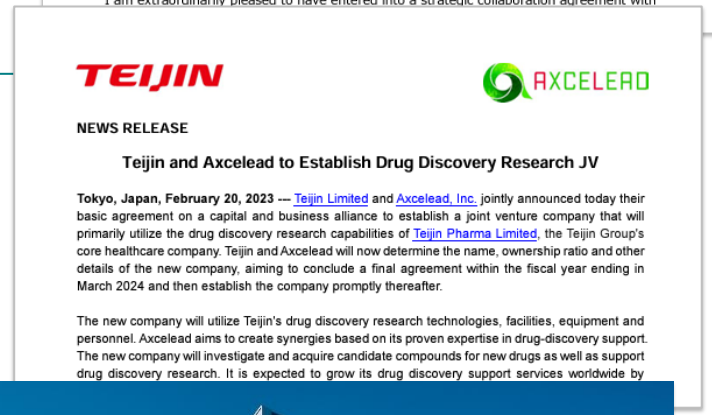
Axcelead DDP and Lilly Enter into Research and Collaboration Agreement

September 5, 2024 – Axcelead Drug Discovery Partners, Inc. (HQ: Fujisawa, Kanagawa, Japan; "Axcelead DDP") announced today that it has entered into a strategic research and collaboration agreement with Eli Lilly and Company ("Lilly") for multiple drug discovery programs.

Axcelead DDP generates drug candidates through its well-established drug discovery capabilities and innovative technologies, including AI. Leveraging its researchers' deep knowledge and extensive experience, Axcelead DDP is positioned to drive innovative advancements in drug discovery.

"I am extraordinarily pleased to have entered into a strategic collaboration agreement with

Established JV in partnership with Teijin in April and started business



TEIJIN AXCELEAD

NEWS RELEASE

Teijin and Axcelead to Establish Drug Discovery Research JV

Tokyo, Japan, February 20, 2023 --- Teijin Limited and Axcelead, Inc. jointly announced today their basic agreement on a capital and business alliance to establish a joint venture company that will primarily utilize the drug discovery research capabilities of Teijin Pharma Limited, the Teijin Group's core healthcare company. Teijin and Axcelead will now determine the name, ownership ratio and other details of the new company, aiming to conclude a final agreement within the fiscal year ending in March 2024 and then establish the company promptly thereafter.

The new company will utilize Teijin's drug discovery research technologies, facilities, equipment and personnel. Axcelead aims to create synergies based on its proven expertise in drug-discovery support. The new company will investigate and acquire candidate compounds for new drugs as well as support drug discovery research. It is expected to grow its drug discovery support services worldwide by

Established the first cGMP-compliant API manufacturing system in the Asia-Pacific region and shipped the first self-amplifying mRNA vaccine API in September

Agenda

1. Introduction
2. Drug Discovery Solutions
3. mRNA CDMO
4. Business Growth Objectives

Agenda

1 **Introduction**

2 Drug Discovery Solutions

3 mRNA CDMO

4 Business Growth Objectives

Axcelead Leads Innovation for Global Healthcare

Purpose

Build a healthy future for people worldwide through a groundbreaking healthcare platform

Vision

Become the world's most trusted healthcare platform company to lead innovation in global healthcare

- Collaborating with a wide variety of academic and industry partners to co-create innovation
- Providing R&D and manufacturing services together with industry-leading technologies to support the development and production of new modalities
- Contributing to infectious disease risk reduction by rapidly manufacturing vaccines during pandemics

- Leveraging diverse data and cutting-edge digital technology to maximize the efficiency of drug discovery and development
- Striving to become a unique global leader in the field

Axcelead Leads Innovation through Healthcare CRO and CDMO Business

AXCELEAD

Axcelead, Inc.
(Holding company)

Drug Discovery Solutions

AXCELEAD Drug Discovery Partners

World-class drug discovery platform CRO

mRNA CDMO

ARCALIS

JV with Arcturus

First GMP-compliant integrated mRNA drug CDMO in the Asia-Pacific region

Rapid Expansion of Outsourcing Market with Horizontal Division in Drug Discovery

Drug discovery process has evolved from vertical integration model to horizontal division model. Outsourcing market of CROs and CDMOs is rapidly expanding as pharmaceutical companies aggressively utilize external resources.

Pharmaceutical Company

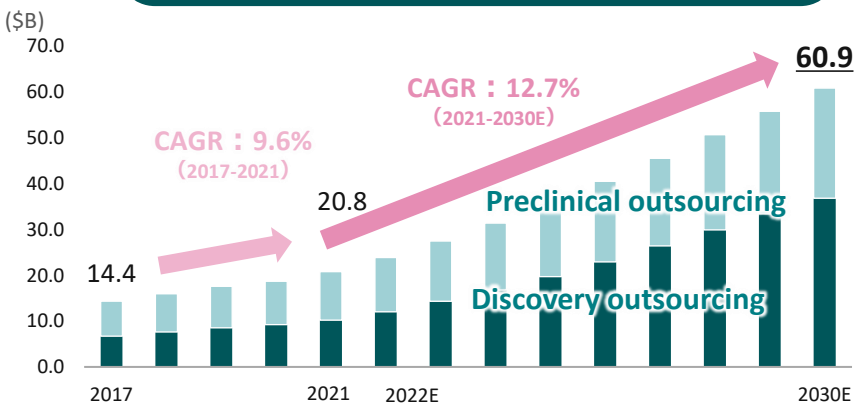
Vertical integration model

Basic Research → Target ID → Lead Generation → Lead Optimization → Preclinical Study → Clinical Development → Commercial

Horizontal division model

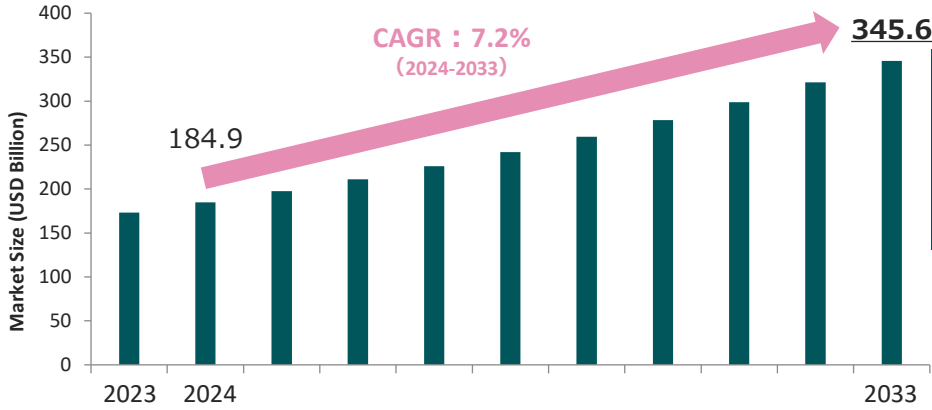
- Discovery CRO
- Clinical CRO CDMO
- CSO

CRO Outsourcing Market



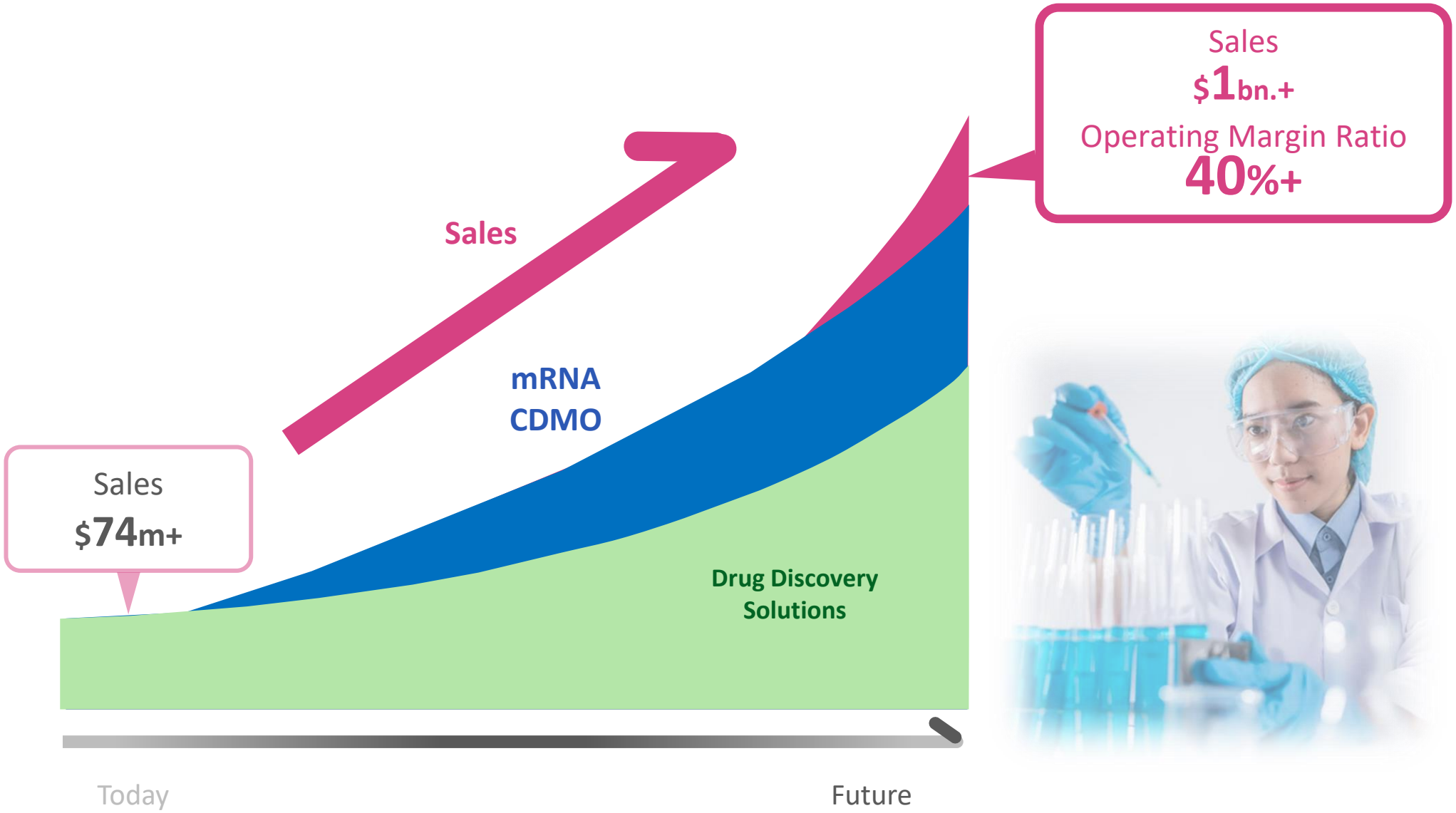
CAGR 12.7% (2021~2030)

CDMO Outsourcing Market



CAGR 7.2% (2024~2033)

Axcelead Group's Strategic Vision for Sales and Operational Profit Growth



Agenda

1 Introduction

2 **Drug Discovery Solutions**

3 mRNA CDMO

4 Business Growth Objectives

Axcelead's Drug Discovery Solutions

Leveraging a comprehensive drug discovery platform that incorporates experienced talent, infrastructure, and research data inherited from pharmaceutical companies,
Axcelead develops its unique Drug Discovery Business

Corporate History

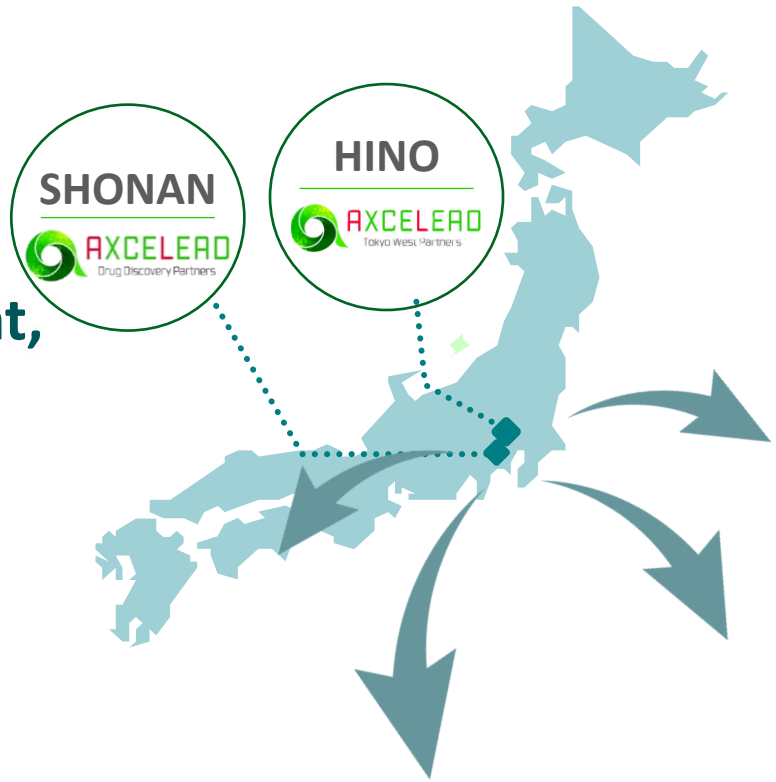
Jul. 2017	◆ Business Initiated by Inheriting the Drug Discovery Platform from Takeda Pharmaceutical Company Limited（SHONAN）
Apr. 2019	◆ Transitioned to a Management Structure under a Fund Operated by Whiz Partners
Apr. 2020	◆ Through a Company Split, Axcelead DDP Became a Subsidiary of the Holding Company Axcelead Inc.
Apr 2024	◆ Launched Axcelead Tokyo West Partners Inc., a Joint Venture Between Axcelead Inc. and Teijin Limited(HINO)

Takeda 2017

TEIJIN 2024

Pharmaceutical-Grade Talent, Infrastructure, and Data

400+ employees	**200+** Advanced Degree Scientists
1000 Legacy projects	**1.2M+** Library



Delivering Drug Discovery Solutions to Global Clients

Contributing to Clients' Drug Discovery Challenges through Axcelead's Pharma-Grade Drug Discovery Platform

Axcelead addresses outsourcing needs of pharmas by advancing its Drug Discovery Platform with talent, technology, data, and partnerships inherited from Pharma

Comprehensive Integrated Drug Discovery

All inclusive drug discovery capability

Target ID & Validation → Hit identification → Lead generation → Lead optimization → IND/NDA enabling study

Pharma Scientist
Provide pharma quality full capability

Seamless Alignment
Organize multi-function seamlessly

Legacy Data
Accelerate drug discovery by legacy data

Boost the Innovation

Legacy Data x AI
Increase success rate of drug discovery with proprietary generative AI

Modality Expansion
From next-generation small molecule to antibody, peptide, and nucleic acid

Network Capability Enhancement
Strengthen network capability through strategic partnerships

Enables Axcelead to create new IP

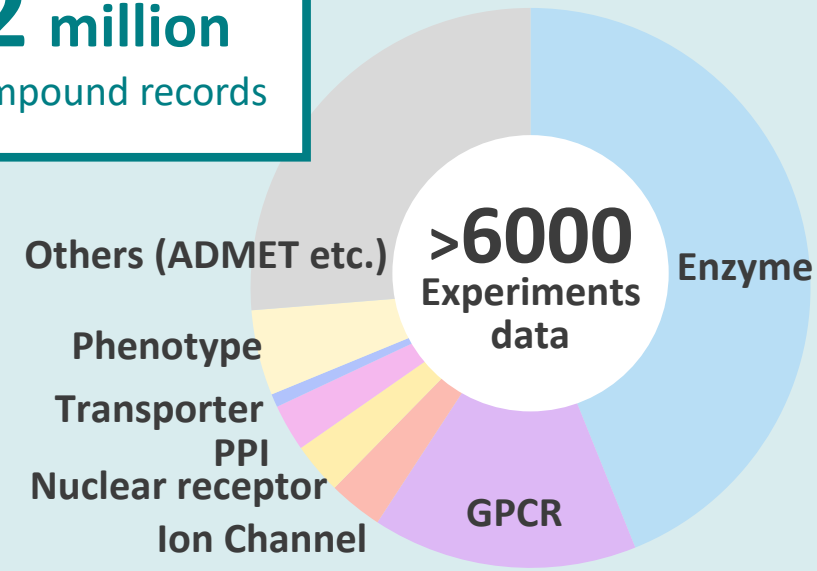
Offer high value for client's drug discovery

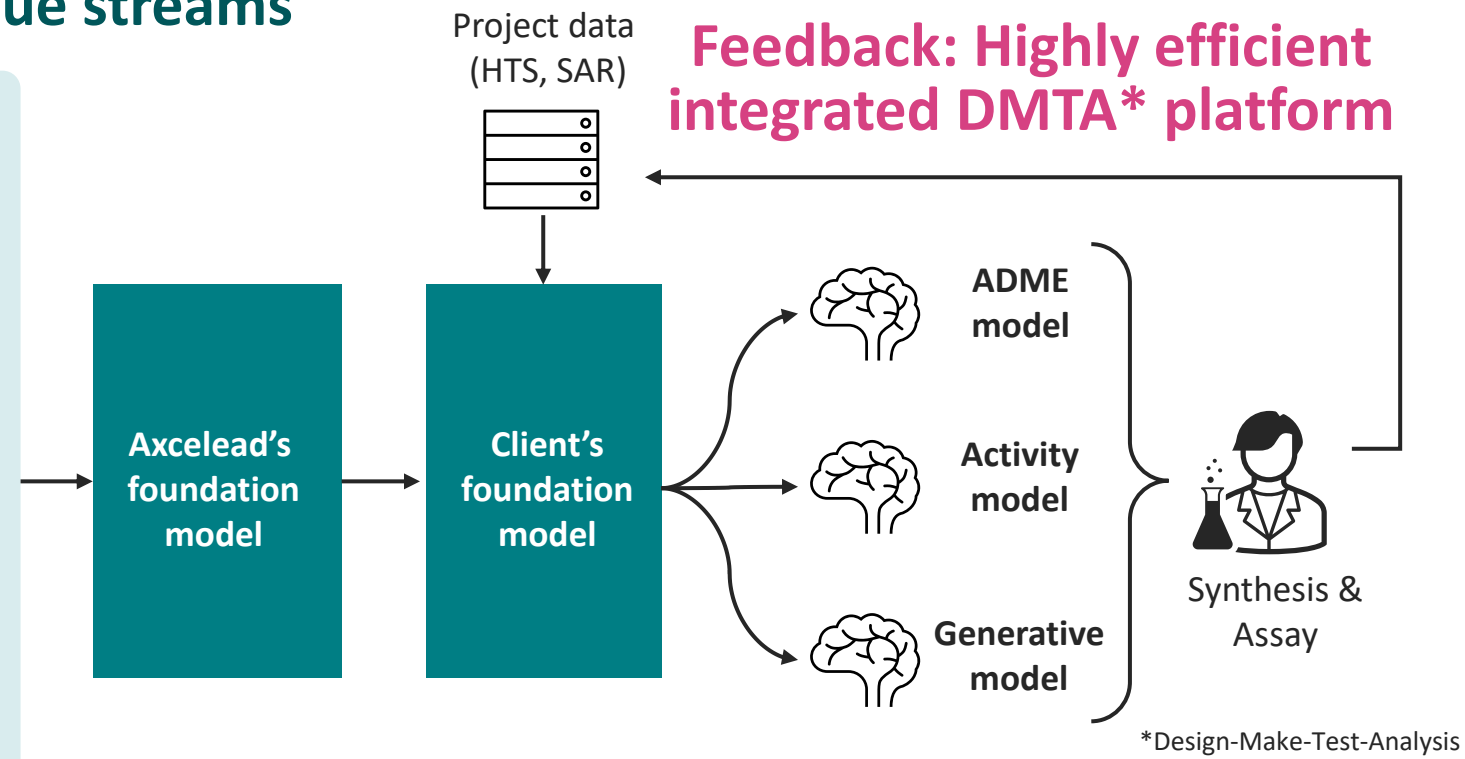
Axcelead's AI Foundation Model Approach based on Proprietary Database and Wet-lab Harmonization

Axcelead's proprietary AI foundation model accelerates drug discovery to reduce timeline to the clinical trials, increasing revenue streams

Axcelead's proprietary database

2 million
Compound records





Deliver promising clinical candidates within 19-27 months (industry standard 36-72 months)

Enhanced Capability for New Modality and Technology

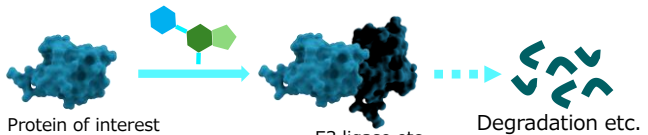
Expanding from small molecule to chemistry-based modalities widely

Targeted Protein Degrader

Induction/Stabilization of protein–protein interactions

e.g. Lenalidomide

Protein for modulation



Protein of interest

E3 ligase etc.

Degradation etc.

RNA-targeted Drug Discovery

High-throughput Affinity Selection Mass Spectrometry for FMN riboswitch RNA binders

Diversity Library: 140,633 cpds

RNA focused Library: 6,400 cpds

FMN riboswitch RNA 5 μM

Compound conc.: each 0.5 μM

Assay format: 400 cpds/pool

Reproducibility test

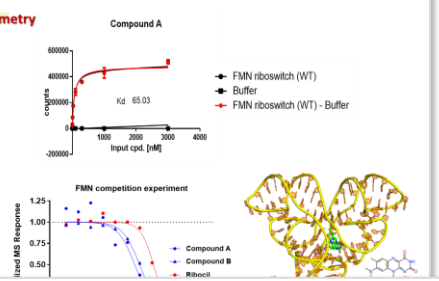
Counter Screen using scramble RNA

Confirmation assay

Diversity Library : 72 hits

RNA focused Library : 7 hits

Kd determination



mRNA Therapeutics

AXCELEAD × ARCTURUS therapeutics

Joint venture with Arcturus

The First Asia-Pacific GMP Standard CDMO of mRNA medicines

Biologics

Next Generation Small molecule

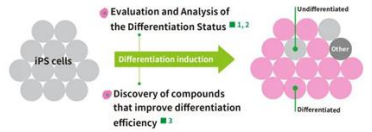
Regenerative Medicine

mRNA therapeutics

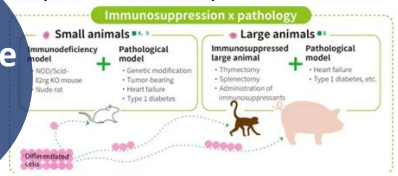
Oligo nucleotide

Regenerative Medicine

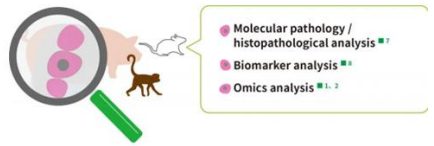
Step 1- Cell Quality Evaluation



Step 2- In Vivo Assay



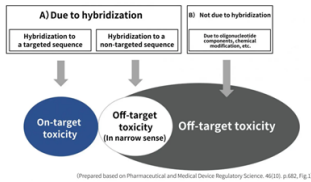
Step 3- Supporting Clinical Practice



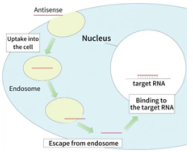
Axcelead DDP Provides Research Support for Regenerative Medical Products.

Oligonucleotide Medicine

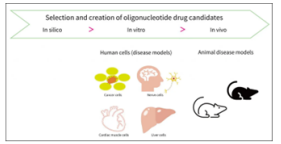
1. Address to challenges in safety



2. Delivery to target tissues and cells



3. Assessment of drug efficacy



Strong support in oligonucleotide drug discovery research, from selection and creation of candidates to preclinical development

Axcelead's Proven Track Record

Axcelead is highly regarded by clients, maintaining a high repeat rate. Also, brand recognition is increasing overseas, leading to a rise in orders

Number of Clients

280+

Customer Repeat Rate

90%

Overseas Sales Ratio

>45% *

・Number of Clients: Total number of clients since the company's founding in 2017
・Customer Repeat Rate: Percentage of clients with two or more contract renewals in FY2024

* As of FY2024 3Q, expected to be maintained through the end of the fiscal year

Axcelead has Earned Recognition of Customers with Business Opportunities: Japan Market almost Covered, Overseas Increasing

In addition to business achievements with major domestic companies, discovery program orders from large overseas pharmas and biotech ventures are increasing

ACADIA · ARTham Therapeutics · AsahiKASEI · あすか製薬株式会社 · astellas
CARDURION PHARMA · Chordia Therapeutics · Daiichi-Sankyo · EAファーマ · エーザイ株式会社
Evommune · FIMECS · FUJIFILM · GEXVal · KAKEN
KYOWA KIRIN · Lilly · maruho · meiji · Mitsubishi Tanabe Pharma
Nissan Chemical CORPORATION · Otsuka · PRISM BioLab · RNA ReboRNA Reborna Biosciences, Inc. · SEEDSUPPLY

NEWS

Axcelead DDP and Lilly Enter into A Researc
Collaboration Agreement

Lilly

Track records of LG/LO from 2017 Q2 to 2024 Q2	Experienced	Achieved Goal*
	64 projects	53 projects

*PJ goal, such as Lead identification, Candidate nomination etc.

2024.09.10

September 10, 2024 – Axcelead Drug Discovery Partners, Inc. (HQ: Fujisawa, Kanagawa, Japan; hereinafter referred to as "Axcelead DDP") announces that it has entered into a Master Service Agreement with Acadia Pharmaceuticals Inc. (HQ: San Diego, CA, USA; hereinafter referred to as "Acadia") to support their goal of discovering and developing innovative and novel medicines to help address unmet medical needs.

Agenda

1 Introduction

2 **Business Strategy (Drug Discovery Solutions)**

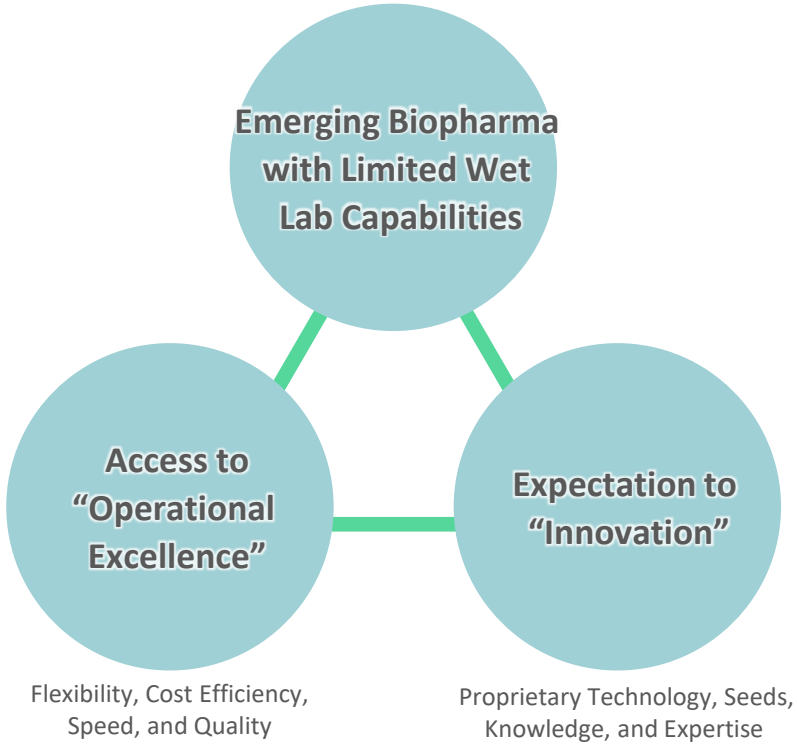
3 mRNA CDMO

4 Business Growth Objectives

Evolving Dynamics in the Drug Discovery Outsourcing Market

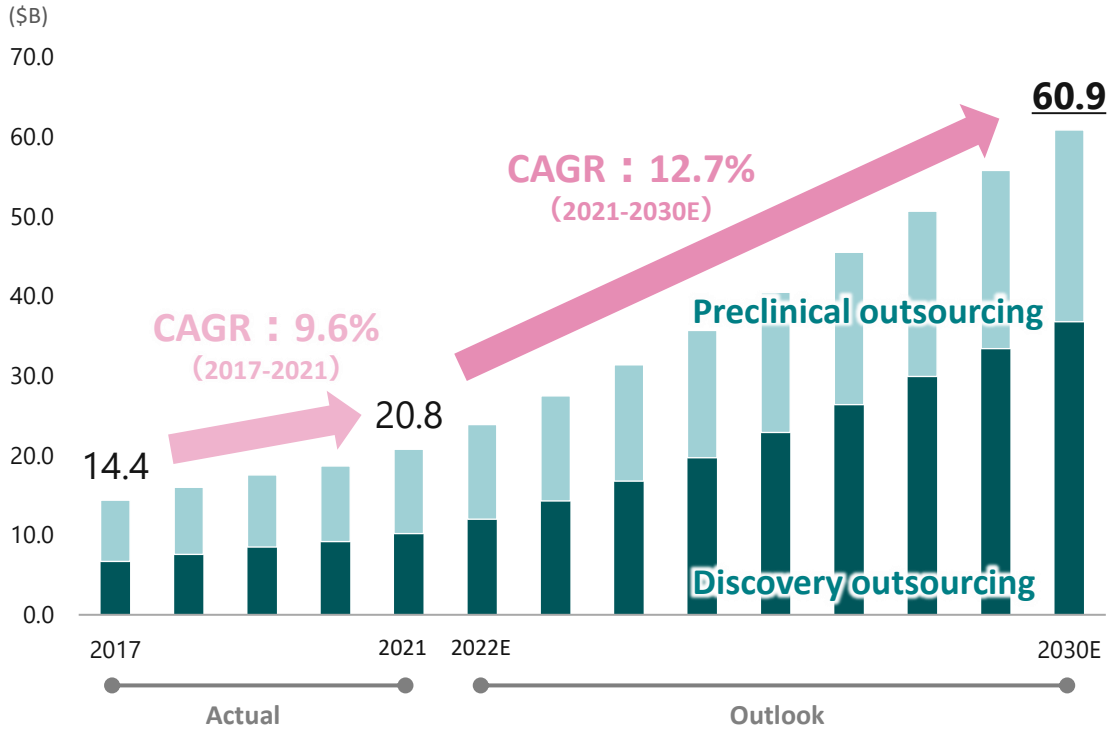
- R&D expenditures in global life science companies are expected to increase *
- The growth rate of the preclinical outsourcing market surpass that of R&D expenditures *
- The U.S. decoupling strategy from China is accelerating the shift among outsourcing market players

Major Growth Driver



Source：Frost & Sullivan

Pre-Clinical Outsourcing Market



* Source: 20220725 WuXi AppTec Investor Day "Industry Trend and Company Strategy"

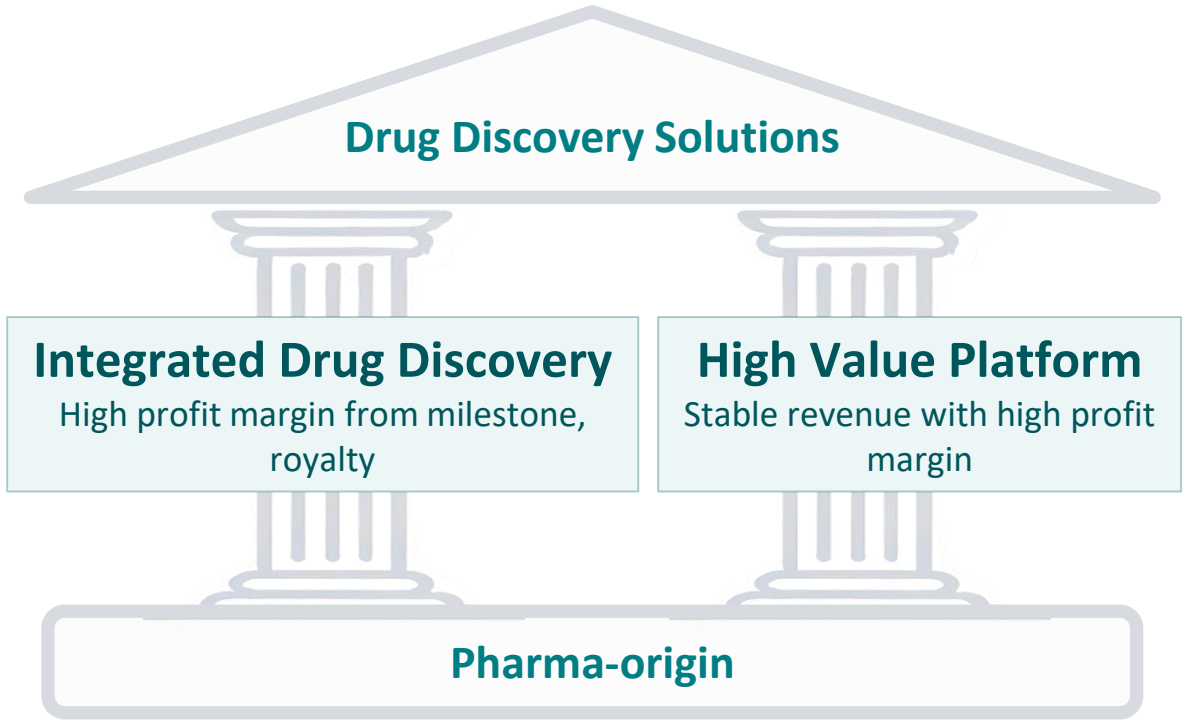
Expectations and Roles of Drug Discovery CROs

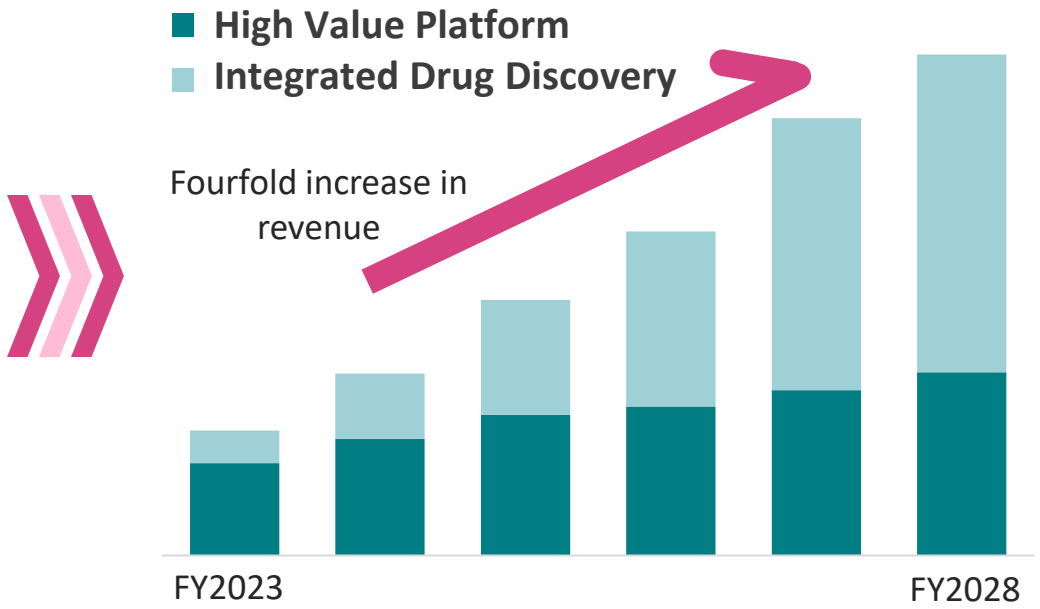
To provide comprehensive and stable solutions to a wide range of drug discovery challenges as a partner, not just an ordinary CROs

	Typical Platform	High Value Platform	Integrated Drug Discovery
Service category	Standardized experimental service	Customized experimental service to solve problem	Drug Candidate
Capability	Experienced technical operation	Experienced scientific expertise with cutting edge technology	Integration of Multiple pharma-quality function
Contract Style	FFS, FTE	FFS	Upfront, Operation fee, Success fee
Representative companies	WuXi, Charles River, Eurofins, SNBL, etc.	Evotec, Axcelead, Sygnature, Charles River, etc.	Evotec, Axcelead, etc.
Contribution to Industry	Operational excellence; cost efficiency, speed, and capacity filling	Solve drug discovery problem by providing customized experiments	Identify candidate through overcoming challenges by itself

Axcelead's Business Strategy

By leveraging the two pillars of High value platform and the integrated drug discovery, Axcelead builds a business structure that enables stable growth based on profitability



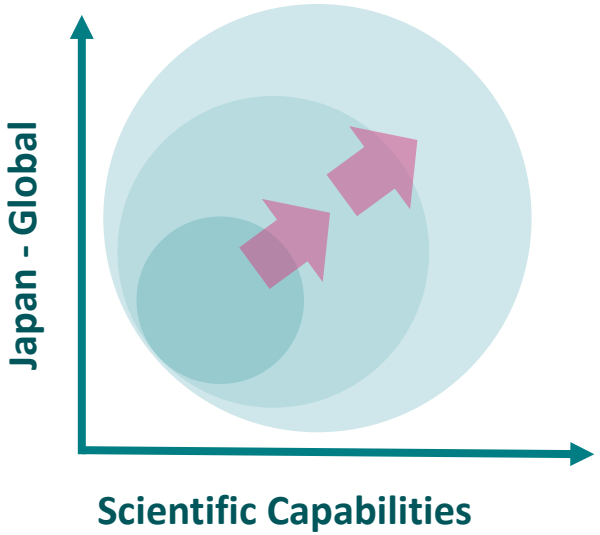


Stable growth with high profitability

Strategy for Drug Discovery Solutions

1 Business expansion from Japan to North America and Europe

- Expand integrated drug discovery business with Large Pharma
- Expand comprehensive order contracts for platform business
- Acquire overseas clients by leveraging local agents and Axcelead US established at San Diego



2 Access to the latest technologies and strengthen drug discovery infrastructure

- Axcelead's proprietary AI/ML model reduces drug discovery timeline by >40%
- Increase integrated drug discovery projects by expanding therapeutic modalities such as targeted protein degrader (TPD), RNA modulator, oligonucleotides, and antibodies (ADC)

Agenda

1 Introduction

2 Drug Discovery Solutions

3 **mRNA CDMO**

4 Business Growth Objectives

Company Overview

ARCALIS, mRNA CDMO

MISSION

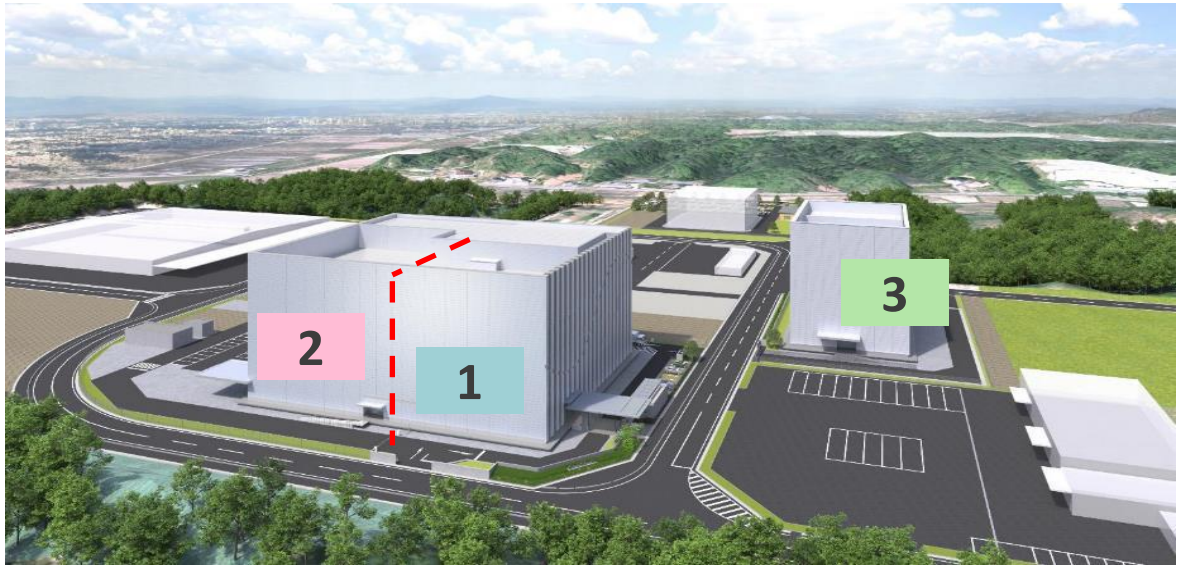
Contribute to universal access to safe, effective, quality and affordable mRNA vaccines and therapeutics by providing end-to-end development and manufacturing

Founded Feb. 2021	**Joint-Venture** U.S. - Japan	**Location** Japan
Industry CDMO	**Technology** mRNA / LNP	**Employee** 113

Business Overview

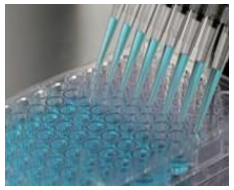
Kashiwa site

- CMC Development
- Non-GMP mRNA/LNP



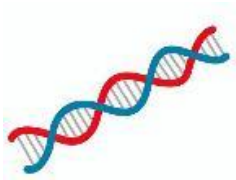
Minamisoma site

- GMP mRNA DS
- GMP LNP Bulk
- GMP Fill and Finish
- Clinical products
- R&D
- GMP mRNA DS



mRNA Drug Discovery

CMC



Plasmid DNA

mRNA DS

LNP Bulk

Fill & Finish

1. DS & LNP (Shipment in Sep. 2024)

2. Fill & Finish (Feb. 2026)

3. R&D Facility (Nov. 2027)

Agenda

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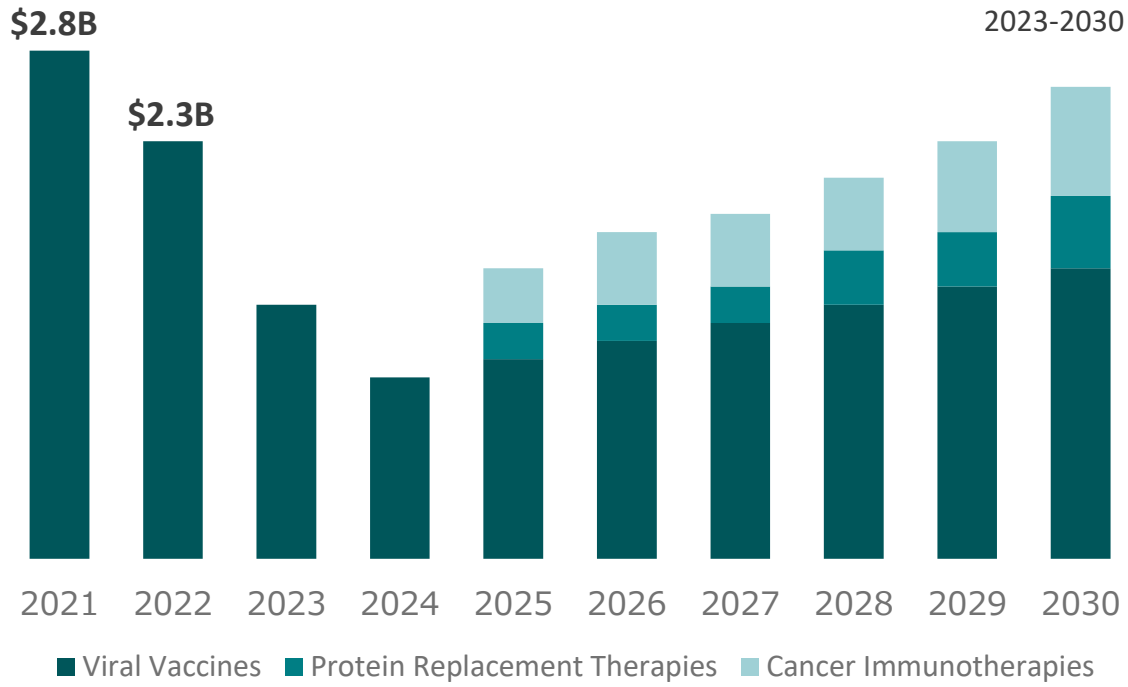
Market outlook and development status of mRNA drugs

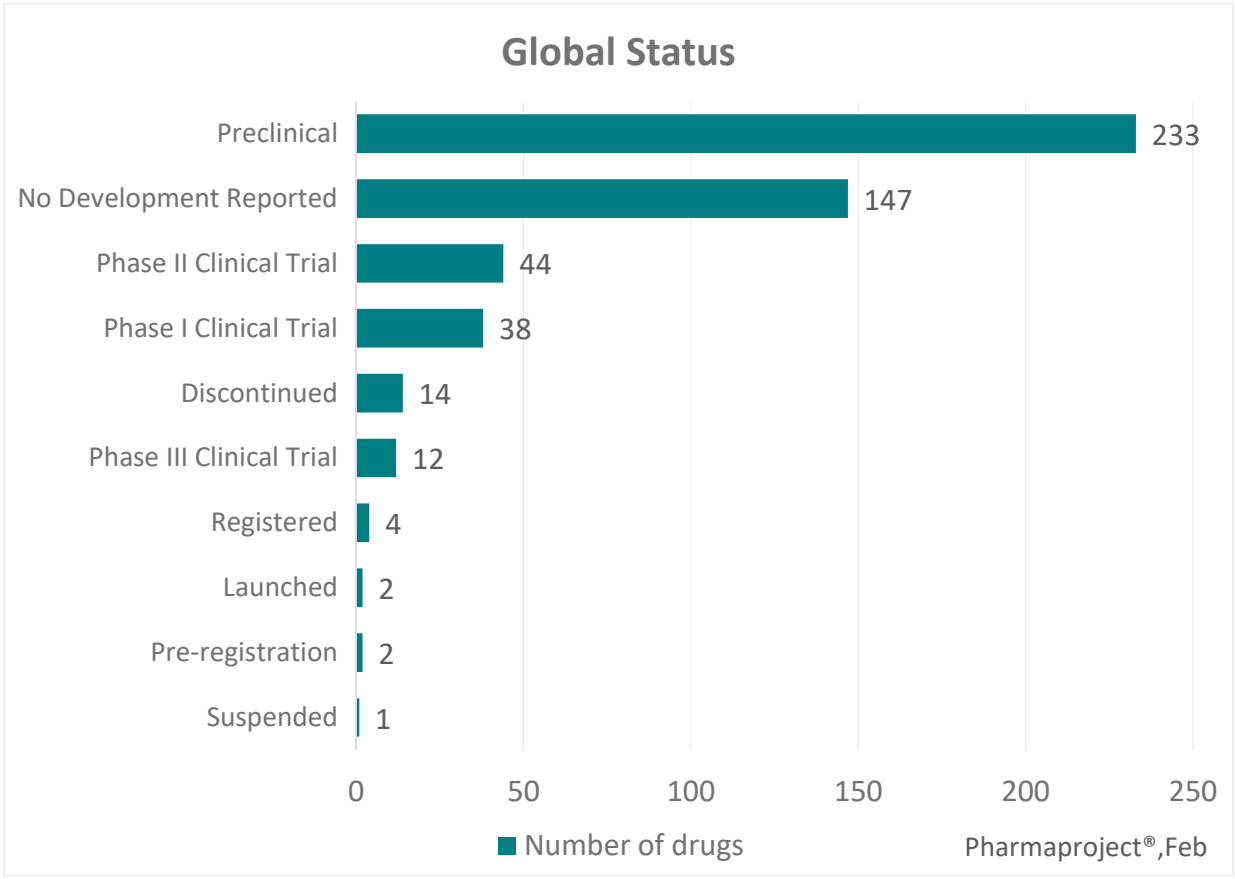
U.S mRNA Therapeutics Contract Development & Manufacturing (CDMO) Market

Share, by Application, 2021-2030 (USD Billion)

11.2%
U.S Market CAGR, 2023-2030



Source: www.grandviewresearch.com

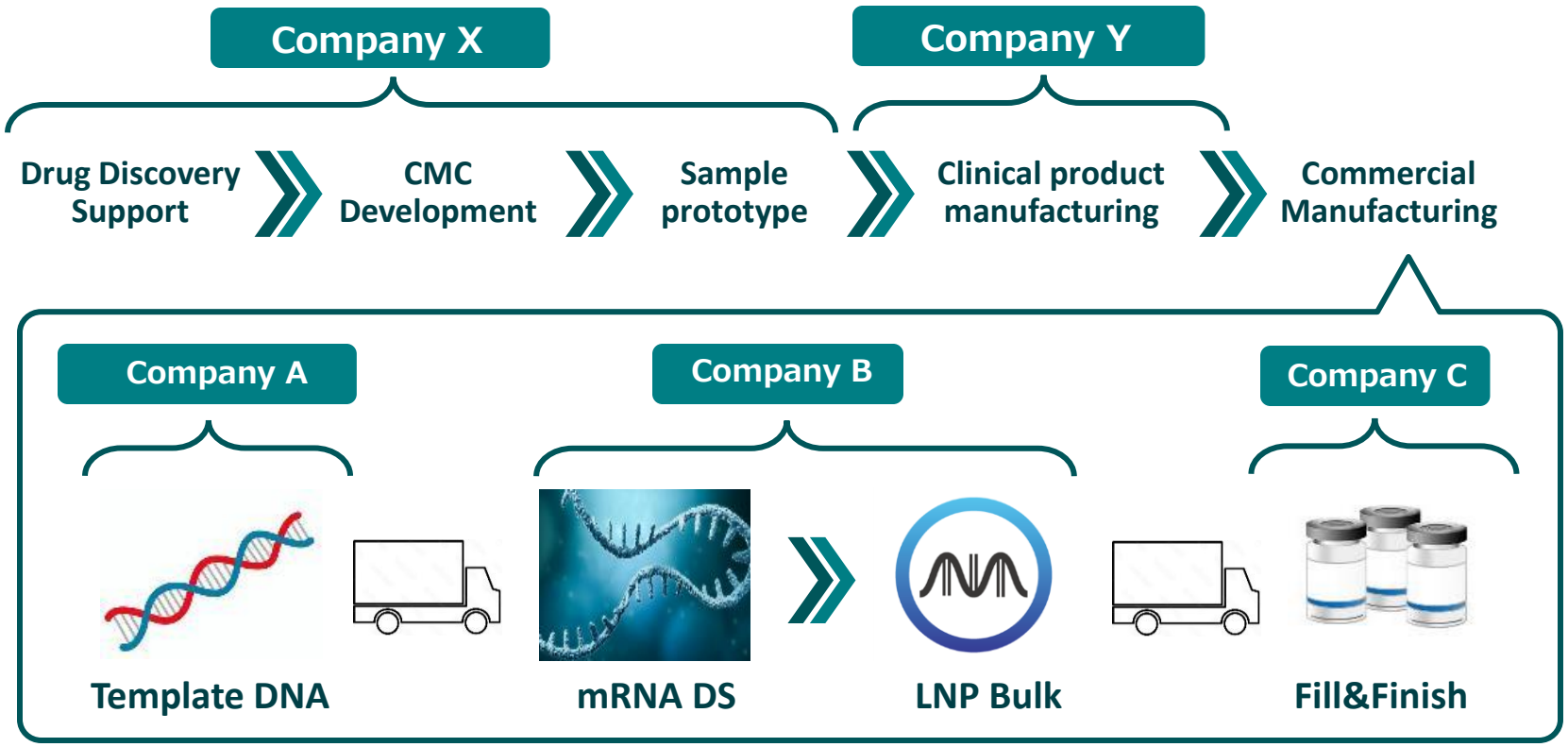


- **mRNA CDMO market will shrink once the COVID-19 pandemic ends, but is forecast to recover, especially in infectious disease vaccines and oncology therapeutics.**
- **Numerous development programs in preclinical stage**

Issues in the development and outsourcing of mRNA production

Fragmented supply chain: development and manufacturing are not completed by a single company

- The company is unable to handle the entire process of DNA synthesis, DS, LNP and formulation in-house.
- The company is able to manufacture samples, but is unable to manufacture Clinical products or commercial products.
- The company is able to manufacture Clinical products, but is unable to provide drug discovery support or process development.



- Increasing complexity of schedule management
- Multiple technology transfers
- Communication burden

In addition to this, there are also

- increased costs
- variations in quality control
- blurred lines of responsibility
- extended lead times
- data consistency and uniformity issues
- stability during transport, etc.

Competitive Landscape

Advantages of ARCALIS:

- **ARCALIS can provide comprehensive support from CMC development to DS/LNP/DP production**
- **ARCALIS has achieved commercial production and clinical use under GMP**

	ARCALIS	aldevron	Catalent	Recipharm
Features	- Integrated production of lDNA/DS/LNP/DP - Clinical and Commercial Manufacturing	- Strong in Plasmids manufacturing - Focus on mRNA CDMO	- Major DS CDMO - Originally strong in formulation	- Largest formulation CDMO
Drug discovery support/ CMC development	○ Responding to new technology developments and CMC development	△ CMC development is supported	△ CMC development is supported	× Specialized in formulation CDMO
Integrated manufacturing of API, LNP and formulation	○ Both clinical and commercial production	△ Clinical use available but not commercial production	△ DS only, not compatible with LNP or F&F	× Bulk LNP and F&F only
Clinical Manufacturing	○ 1L reactor for clinical production will be installed	○ Clinical materials can be performed up to F&F	△ Small quantities may not be accepted	△ Small quantities may not be accepted?
Commercial Manufacturing	○ Plan to operate 30L scale	× Not for commercial use	△ DS can be scaled to 100g	△ Very large capacity for F&F
Location	Japan	US	US	Sweden

Our Services

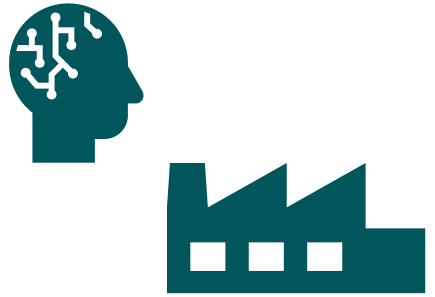
Research
（Search, Optimization, Clinical trial preparation）

- **Template DNA - mRNA manufacturing**
- **LNP/formulation development**
- In vitro/In vivo evaluation
- ADME-Tox test

Development
（Manufacturing process & Analytical method development）

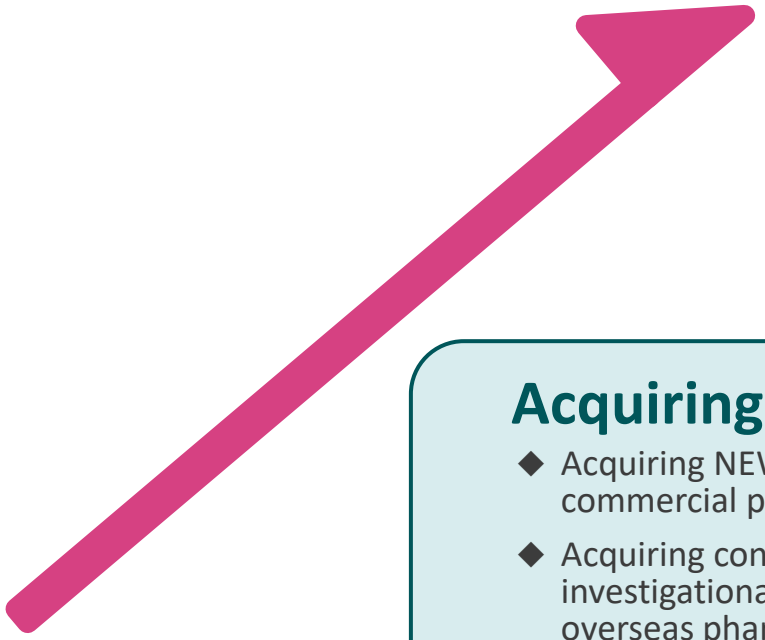
- CMC Development of Template DNA - L.DNA （outsource）
- **DS CMC Development**
- **DP CMC Development**

Manufacturing
（GMP manufacturing）



- Template DNA - L.DNA analytical validation （outsource）
- **DS GMP Manufacturing /Analytical Validation**
- **DP GMP Manufacturing /Analytical Validation**
- **Fill and Finish**
- **Template DNA manufacturing**

Growing business through each customer supply-phase approach



Acquiring IDDS* projects

We have been awarded a contract to manufacture mRNA drug candidates and non-clinical test substances, and we are working to link this to clinical trial drugs and commercial production.

KSF

- **Establishment of proprietary technologies with competitive advantages**
- **Selection, implementation and establishment of LNP-mRNA technology**

Acquiring NEW customer business

- Acquiring NEW customers' projects by leveraging our track record of commercial production of mRNA
- Acquiring contracts for expanded production of approved products and investigational drugs for development products from domestic and overseas pharmaceutical companies

KSF

- **ARCT-154 approval, launch and shipment results**
- **cGMP, EMA inspection results**
- **Securing production volume to meet customer needs**

Strengthening partnerships with existing customers

Strengthened partnerships starting with ARCT-154 to win pipeline contracts for CSL and Arcturus

KSF

- **Strong communication with existing customers**
- **Securing production volume to meet customer needs**

IDDS* Integrated Drug Discovery Service

Agenda

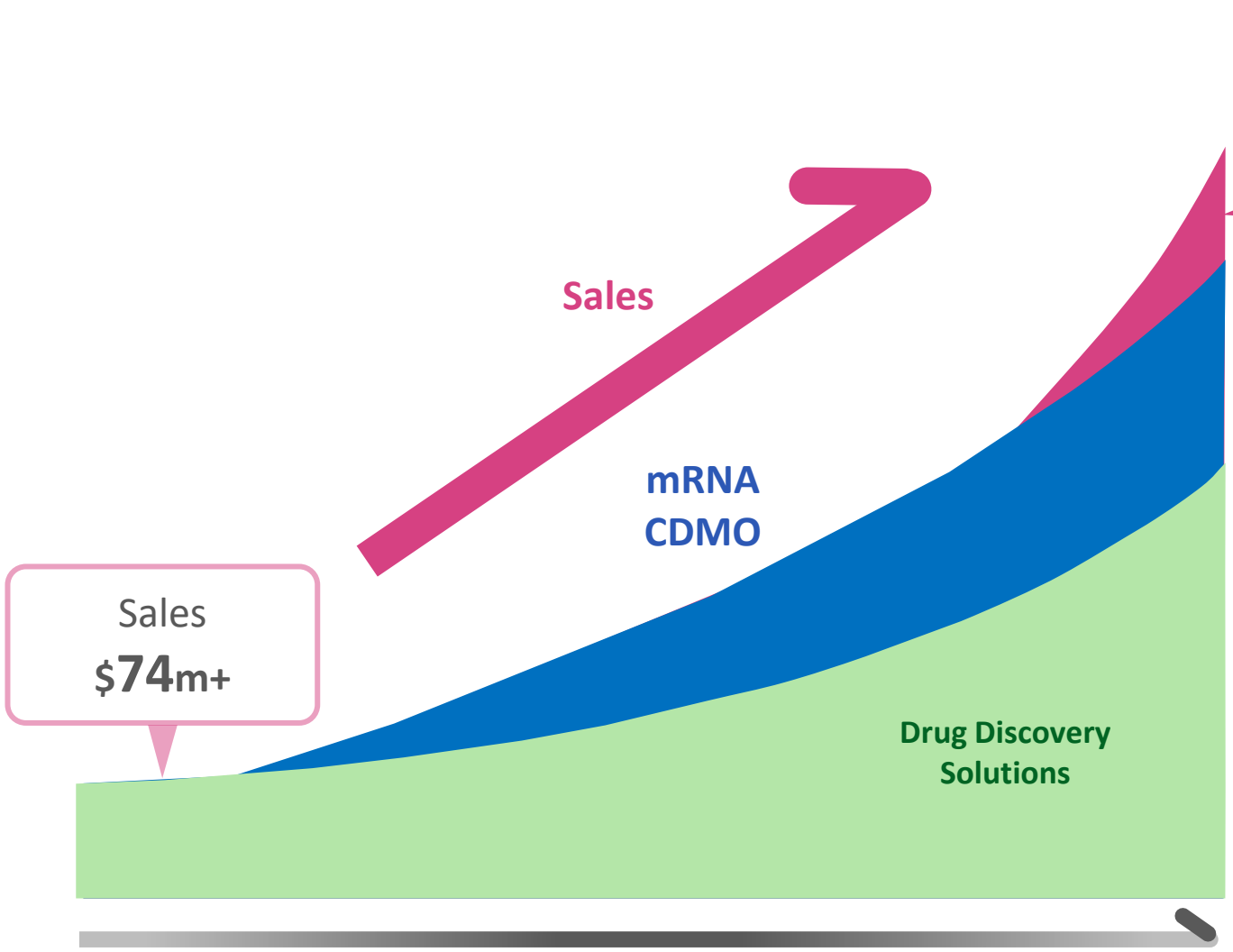
1 Introduction

2 Drug Discovery Solutions

3 mRNA CDMO

4 **Business Growth Objectives**

Axcelead Group's Strategic Vision for Sales and Operational Profit Growth



Sales
$1bn.+
Operating Margin Ratio
40%+

THANK YOU!

https://axcelead-hd.com