



FY2026/ Q2 Financial Results Materials



August 2026

- ◆ This document includes forward-looking statements regarding AnGes' current outlook, forecasts, targets, and plans. Forward-looking statements are based on information currently available and on management's judgment. Actual results may differ materially due to various risks and uncertainties. Accordingly, you should not place undue reliance on these forward-looking statements. AnGes has no obligation to update or revise these statements in light of new information, future events, or other findings.
- ◆ The risks and uncertainties described above include changes in the economic environment surrounding AnGes, progress in research and development, regulatory approvals, and revisions to laws and regulations in Japan and abroad.

1 Overview of First Half FY2026 Financial Results

2 Key Topics in the First Half of FY2026

- ① HGF Gene Therapy Product
- ② NF- κ B Decoy Oligo DNA
- ③ Tie2 Receptor Agonist (AV-001)

3 Other Topics

- ④ ACRL Testing Business
- ⑤ EmendoBio Genome Editing Technology
- ⑥ Financing Activities

01

Overview of First Half FY2026 Financial Results

FY2025 Q2 Consolidated Financial Results

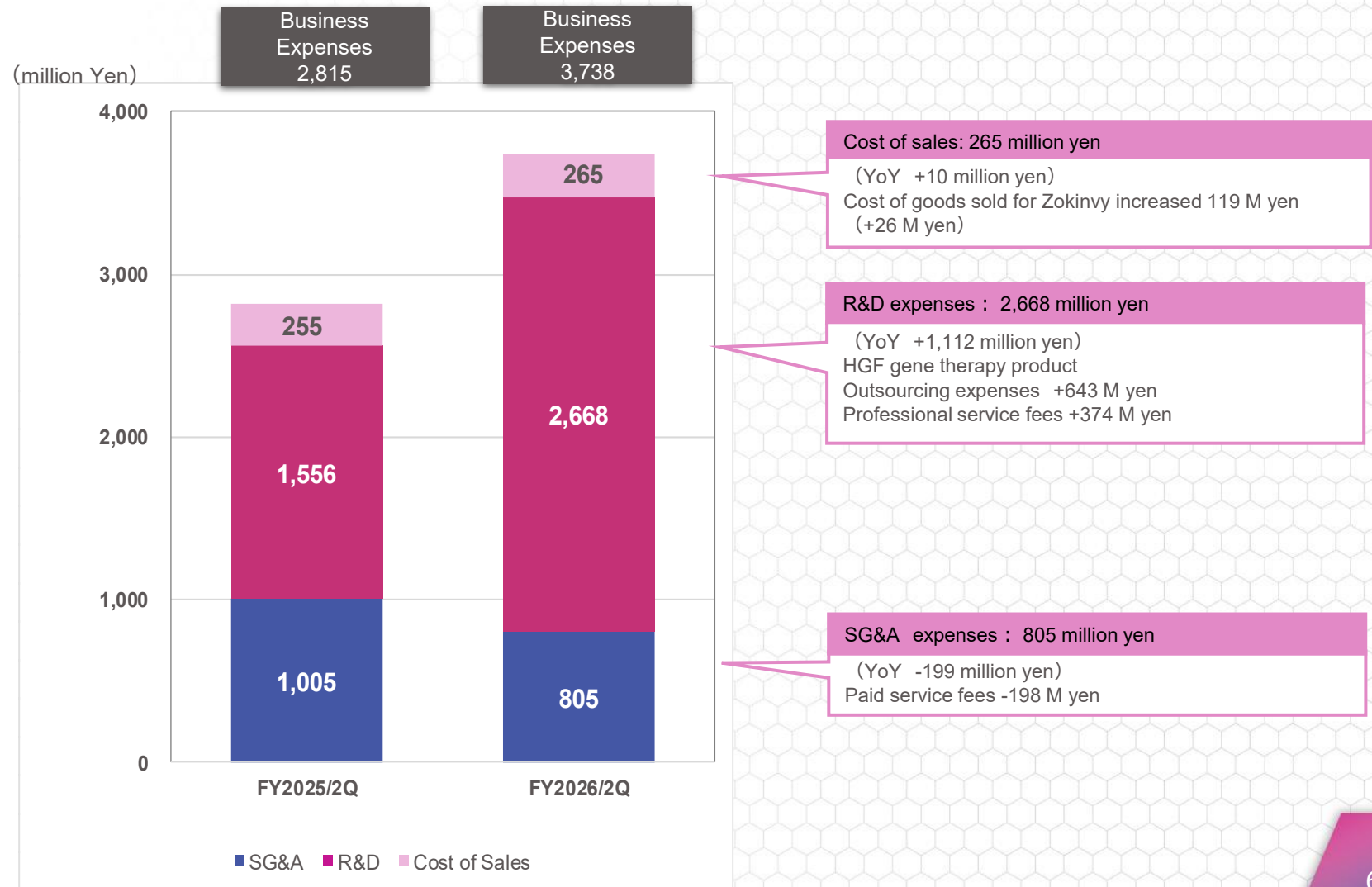
(Million Yen)

	FY2024/2Q	FY2025/2Q	Increase /Decrease
Revenues	414	502	87
Business Expenses	2,815	3,738	923
Operating Profit	-2,400	-3,236	-835
Non-operating income/expenses	-1,498	675	2,173
Ordinary Profit	-3,898	-2,560	1,338
Extraordinary income/Expenses	0	-58	-58
Profit	-3,966	-2,613	1,352

- Revenue increased primarily due to higher sales of Zokinvy.
- Operating expenses increased significantly because of higher R&D expenditures related to BLA* preparation for the HGF gene therapy product.
- Non-operating income and expenses improved substantially due to foreign exchange movements.

*BLA:Biologics License Application

Breakdown of Business Expenses



Consolidated Balance Sheet Highlights

(million yen)

	FY2024	FY2025/2Q	Increase /Decrease
Current assets	4,386	2,619	-1,766
Cash and deposits	1,882	281	-1,600
Non-current assets	1,019	1,040	21
Total assets	5,405	3,660	-1,745
Liabilities	2,329	3,454	1,124
Net assets	3,076	205	-2,870

Current Assets

- Cash and deposits: 281 M yen (-1,600 M yen)
- Financing inflow: 1,178 M yen

Non-Current Assets

- 1,040 M yen (+21 M yen)

Liabilities

- Accounts payable 956 M yen (+413 M yen)
- Accrued liabilities 549 M yen (+315 M yen)
- Corporate bonds 591 M yen (+591 M yen)

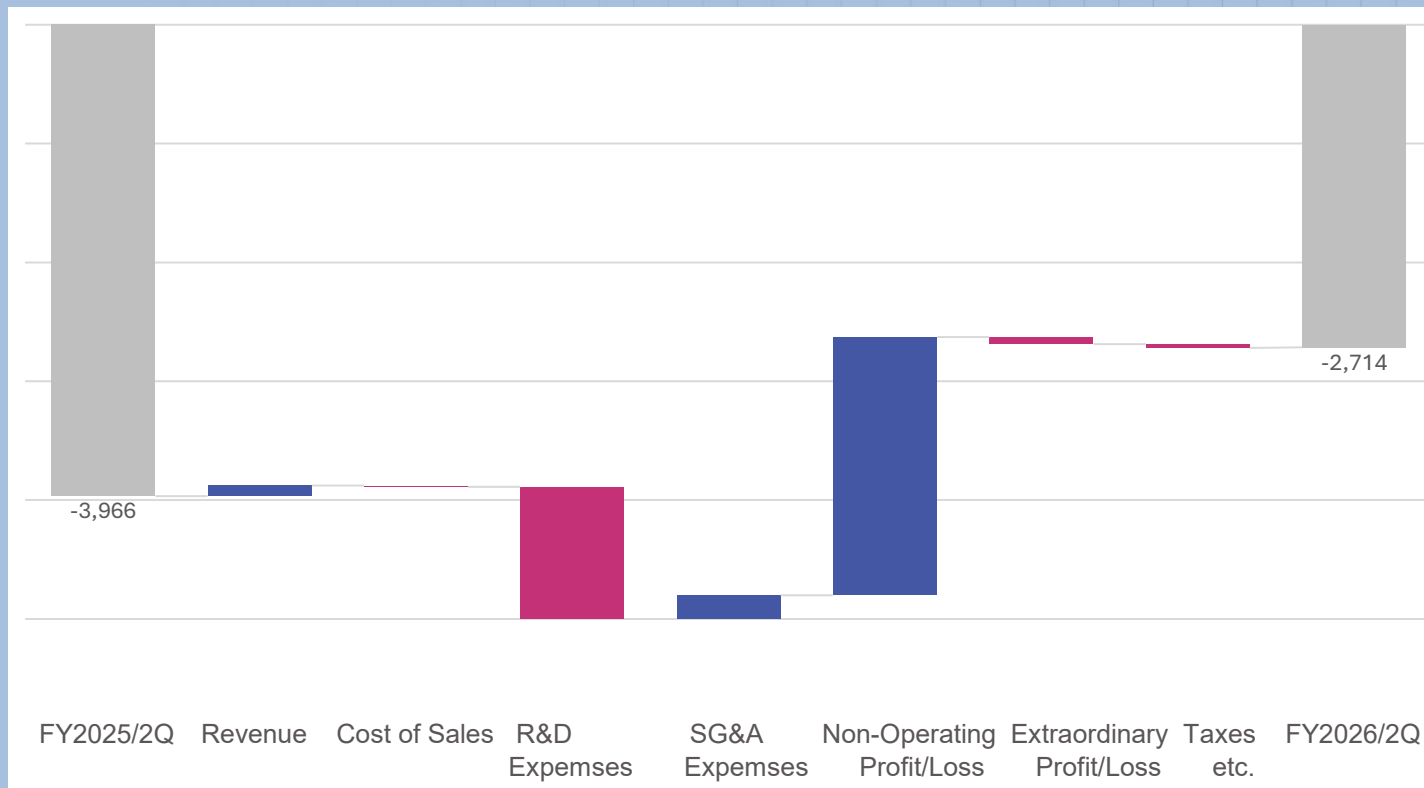
Net Assets

- Capital stock: 40,499 M yen (+270 M yen)
- Capital surplus: 8,746 M yen (+270 M yen)
- Retained earnings: -54,396 M yen(-2,714 M yen)

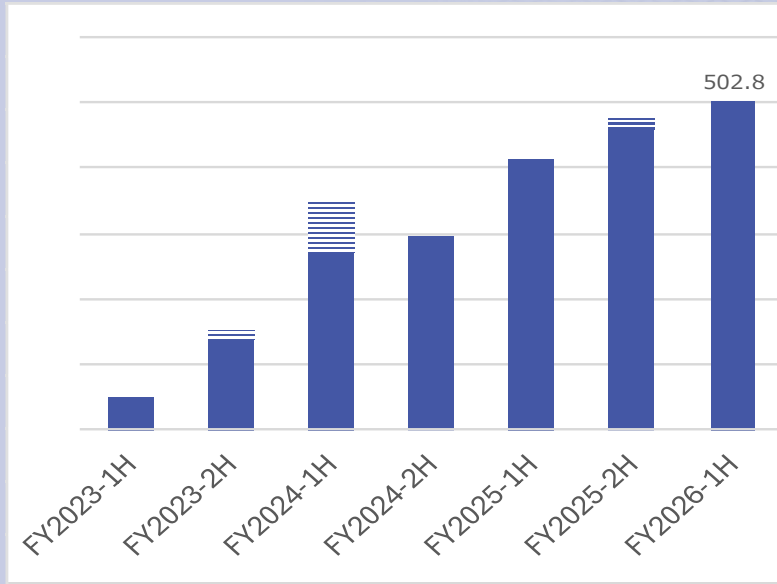
Factors Affecting Net Profit/Loss for the Period

FY2026 / 2Q Results Factors for Increase/Decrease (YoY)

million yen



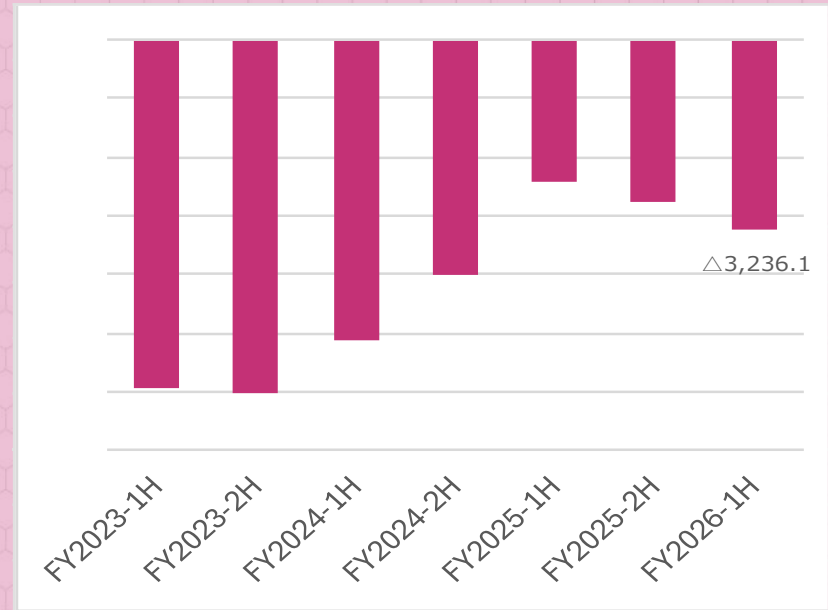
Business Revenue



Operating revenue increased

- Higher sales of Zokinvy
- Stable testing volume for expanded newborn screening services at ACRL

Operating Profit/Loss



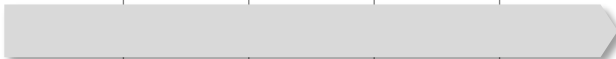
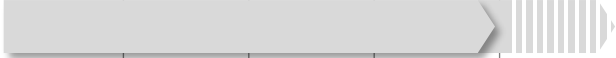
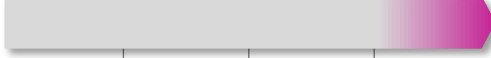
Expenses increased in preparation for the U.S. BLA filing of the HGF gene therapy product

- R&D spending increased due to manufacturing activities for commercial launch preparation

02

FY2026/ 2Q Topics

Status of Our Development Projects

Project	Region	Licensing /Partner	Formulation	Indication	Basic Research	Non-clinical trials	Clinical trials			Application Review	Approval
							Phase I	Phase II	Phase III		
HGF gene therapy product (bepelminogen perplasmid)	Japan	—	Injectable	Chronic arterial occlusion						 Under consideration while monitoring progress in the United States	
	United States	—	Injectable	Chronic Limb-Threatening Ischemia (CLTI)							
	Israel Turkey	Kamada Er-Kim	Injectable	Chronic arterial occlusive disease							
NF-κB decoy oligodeoxynucleotide	Japan	—	Injectable	Chronic discogenic Low back pain							
DNA vaccine	Australia	—	Injectable	Hypertension							
Tie2 receptor agonist	United States	Vasomune	Injectable	Acute respiratory distress Syndrome (ARDS)							

FY2026/ Q2 Topics

1

Progress of HGF Gene Therapy Product

2

Status of NF- κ B Decoy Oligo DNA

3

Status of Tie2 Receptor Agonist (AV-001)

FY2026/ Q2 Topics

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Major Progress of the HGF Gene Therapy Product in FY2026 1H

Topic 1

Completion of FDA Type B Meetings

Following the Type B Clinical Meeting held in January regarding the BLA filing strategy, the Company conducted a Type B CMC Meeting in May and reached agreement with the FDA on the overall BLA submission strategy.

Topic 2

Confirmation of the Use of the Name "COLLATEGENE" in US

The FDA and the U.S. Patent and Trademark Office confirmed that "COLLATEGENE®" may be used in the United States. The United States Adopted Names Council (USAN) adopted "beperminogene perplasmid" as the nonproprietary name of the product.

Topic 3

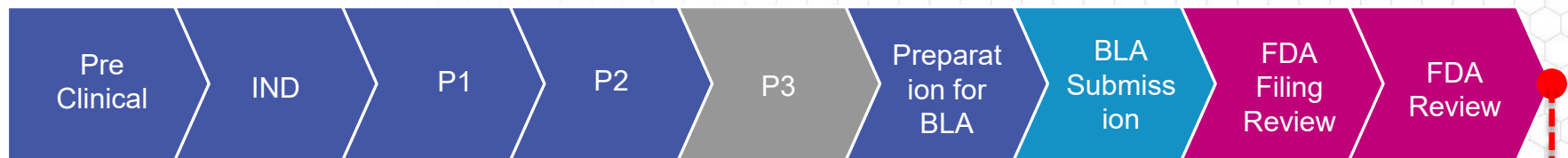
Pre-BLA Meeting Not Required

Through written communication with the FDA, the Company received sufficient responses regarding the planned BLA submission package. As a result, the FDA confirmed that a formal Pre-BLA Meeting was unnecessary, enabling the Company to proceed directly to Rolling Submission.

FDA Biologics Approval Process

Based on favorable Phase 2 clinical trial results in US, discussions with the FDA enabled completion of clinical development without conducting a Phase 3 study

General process for application and approval



Process of HGF Application and Approval



As the product has been granted Breakthrough Therapy Designation, it is eligible for intensive guidance from the FDA and an enhanced review process, including eligibility for rolling submission.

Rolling Submission

Instead of waiting until all application components are completed, submission occurs sequentially as each section becomes available. This approach allows FDA review to start earlier and may shorten the overall time to approval.

Current Status of U.S. BLA Filing

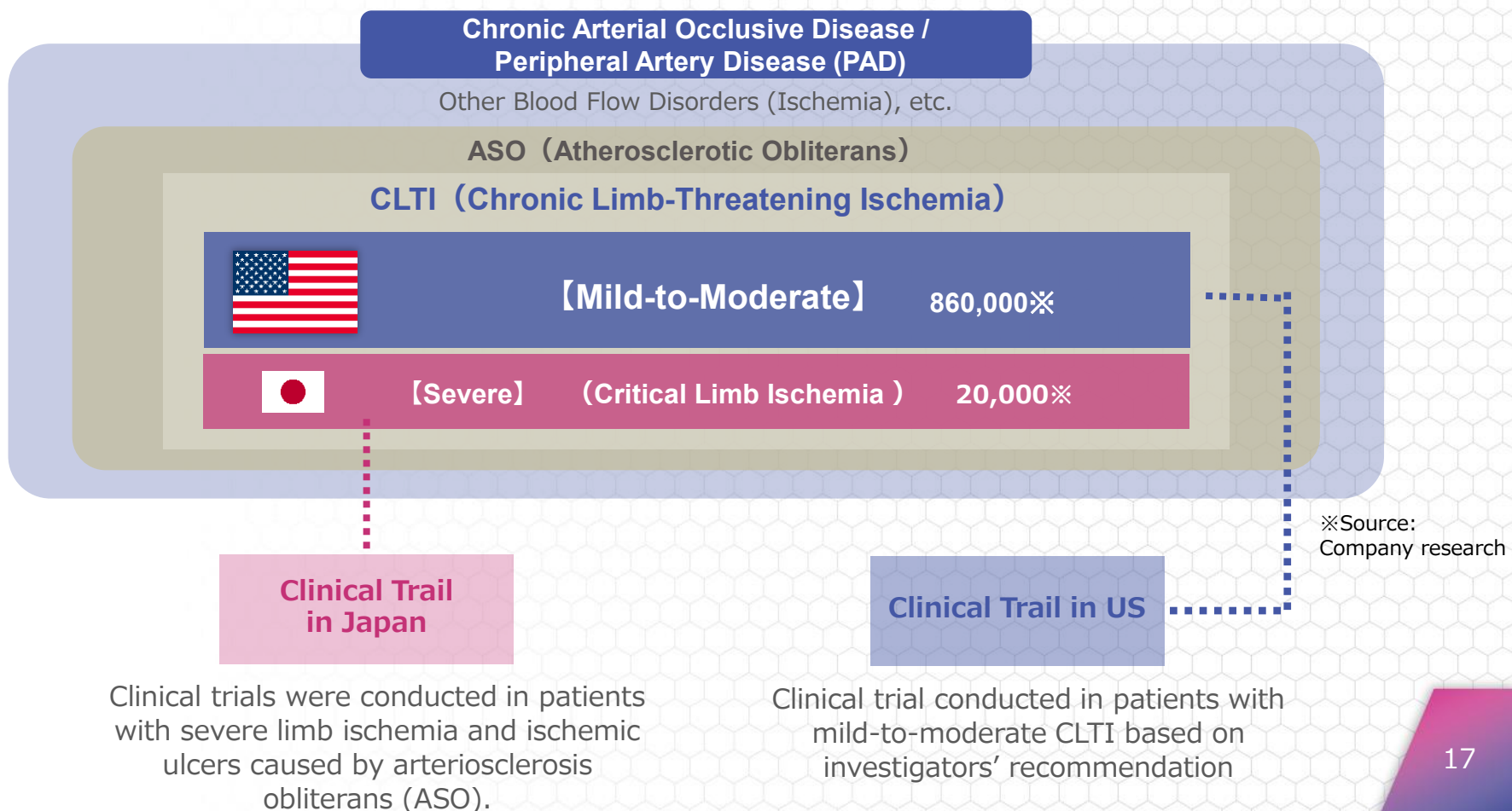
Completed FDA discussions (Clinical & CMC) and the Pre-BLA Meeting process
Initiated Rolling Submission and advancing the BLA review process under Priority Review



FDA review target:
Within 6 months of submission

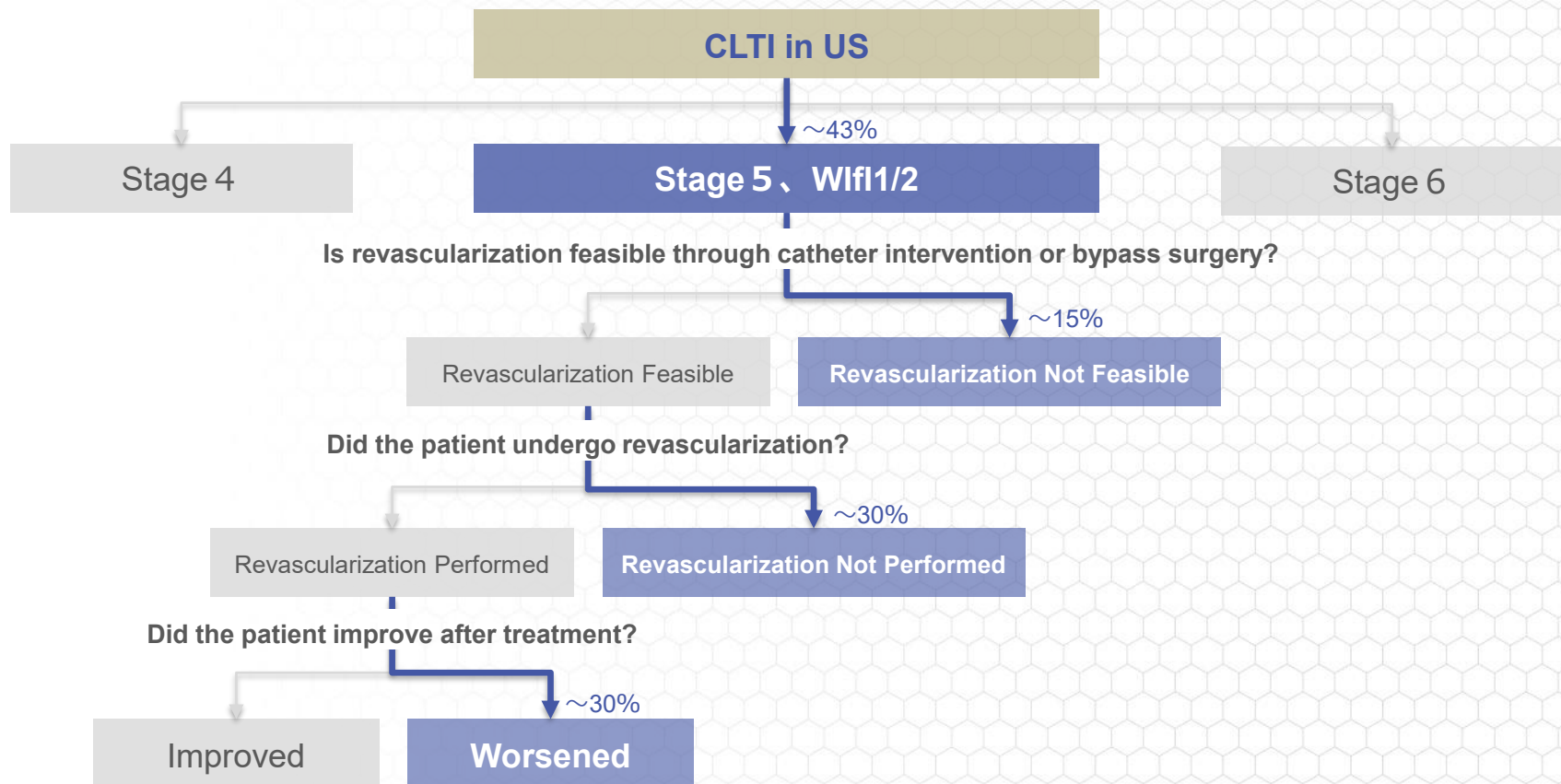
Comparison of HGF Clinical Trial Populations in Japan and US

Following investigators' recommendation that early intervention is critical, a late Phase 2 trial was conducted in US in patients with mild to moderate CLTI.



Target Patients for the HGF Gene Therapy Product

Targeting patients who are unsuitable for revascularization, have not undergone revascularization, or have experienced worsening outcomes after revascularization.



FY2026/ Q2 Topics

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NF-κB Decoy Oligo DNA

A paper reporting the results of a late Phase 1 clinical trial of NF-κB Decoy Oligo DNA in patients with discogenic low back pain in US was published in The Spine Journal, the official journal of the North American Spine Society (NASS).

In the 10 mg Dose Group

- **Pain was reduced in 77.4% of patients** participating in the clinical trial, with nearly complete resolution of pain in approximately half of the patients.
- Improvement in intervertebral disc height from baseline suggests recovery of damaged intervertebral discs.

The ongoing Phase II clinical trial in Japan is targeting completion of patient enrollment during 2026.

FY2026/ Q2 Topics

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Status of Tie2 Receptor Agonist (AV-001)

Tie2 Receptor Agonist (AV-001)

**Being Evaluated in a Phase 2 Clinical Trial in US for the Treatment of
Acute Respiratory Distress Syndrome (ARDS)**

**Target enrollment has been completed, and additional patients are currently
being enrolled to replace dropouts**



Targeting Completion of Enrollment in 2026/3Q

Granted Fast Track Designation by the FDA

- **More frequent meetings and communications with the FDA**
- **Expedited approval and Priority Review**
- **Eligibility for Rolling Submission, allowing portions of the marketing application to be submitted and reviewed on an ongoing basis**

Future Development of AV-001

Initiation of a New Investigator-Initiated Trial

Evaluating the potential of AV-001 to mitigate cognitive decline and preserve white matter integrity by reducing dialysis-associated cerebral edema

Up to 90% of Patients with End-Stage Renal Disease Undergo Hemodialysis



Hemodialysis can lead to symptoms such as confusion, delirium, and long-term cognitive decline
Among patients aged 55 years and older, approximately 70% experience moderate to severe cognitive impairment

Supported by a grant from the Heart & Stroke Foundation of Canada, the study aims to stabilize cerebral blood vessels exposed to significant circulatory stress during hemodialysis.

Patient dosing commenced in March 2026.

Expanded Collaboration Agreement Covering All Disease Indications for AV-001

03

Other Topics

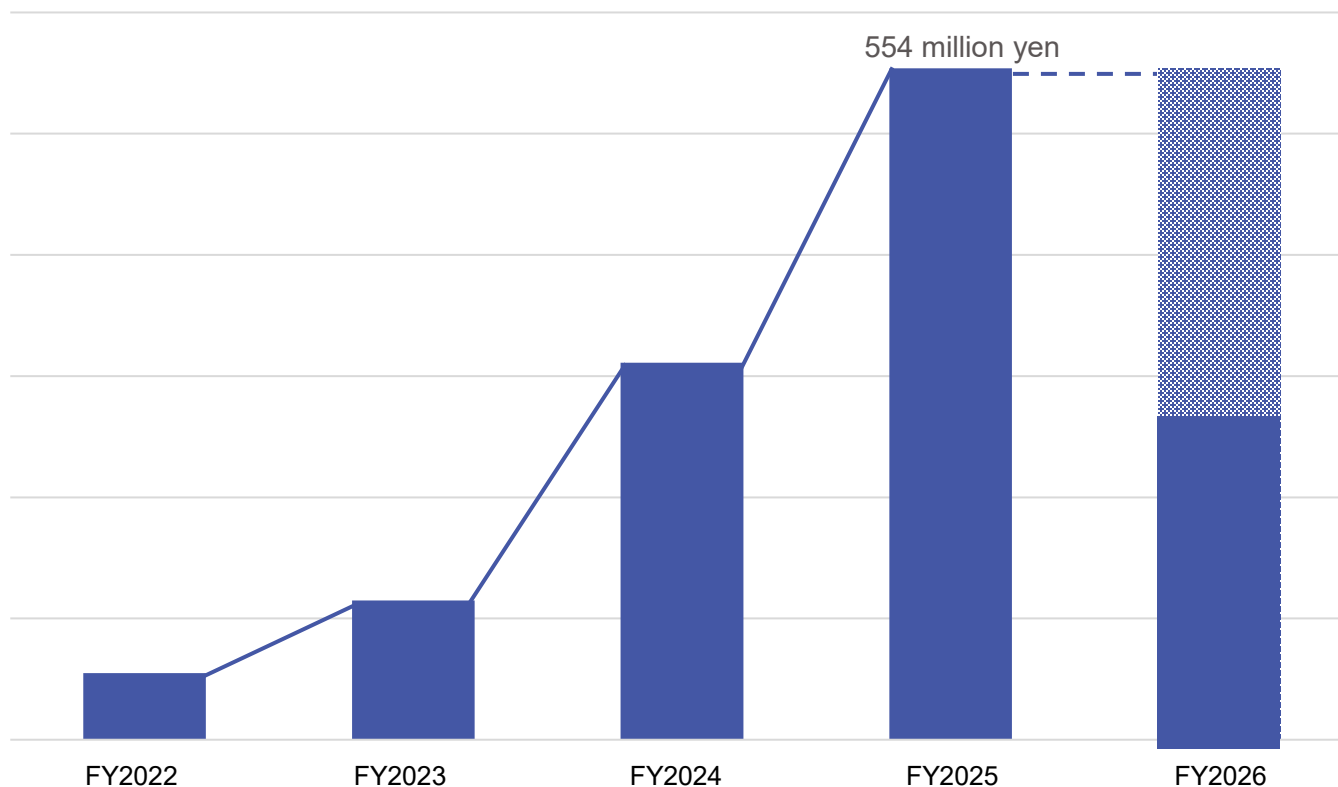
4 ACRL Testing Business

5 EmendoBio Genome Editing Technology

6 Financing Activities

Update on Expanded Newborn Screening Services

Fee revenue from expanded newborn screening services continues to grow steadily



Continue efforts to expand the customer base and broaden the range of diseases covered by the testing services.

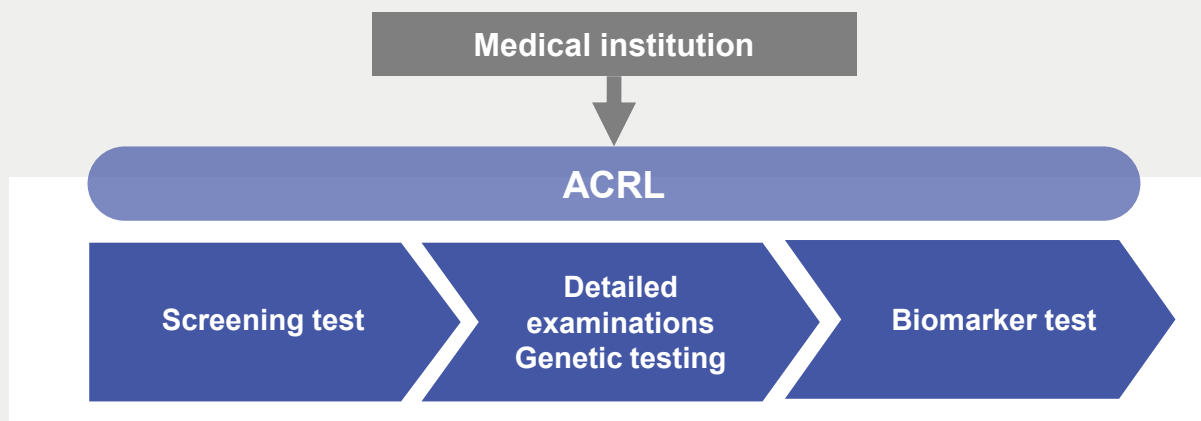
Evaluate strategic options, including expansion of testing services and collaborations with external partners.

One-Stop Testing Services for Rare Genetic Diseases

Lysosomal disorders are associated with a high rate of false-positive* screening results. This places a significant burden on patients' families and healthcare professionals.

Developed and launched a testing service that utilizes biomarker testing as a secondary screening method to identify and eliminate false-positive results.

ACRL has established an integrated platform capable of providing a comprehensive range of testing services for rare genetic diseases.



*False positive: A screening test result indicating the presence of a disease when the individual does not actually have the disease.

Other Topics

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ACRL Testing Business

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EmendoBio Genome Editing Technology

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Financing Activities

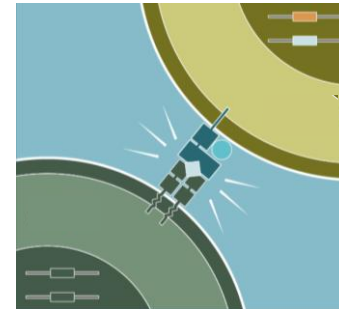
Summary of EmendoBio License Agreement

In 2024, EmendoBio expanded its non-exclusive license agreement with Sweden-based Anocca for the use of the OMNI nuclease, **broadening the scope of permissible applications.**

Engineering Artificial T Cells (TCR-T Cells) that Recognize Cancer-Specific Antigens

Anocca holds a diverse library of TCR receptors specific to various cancers.

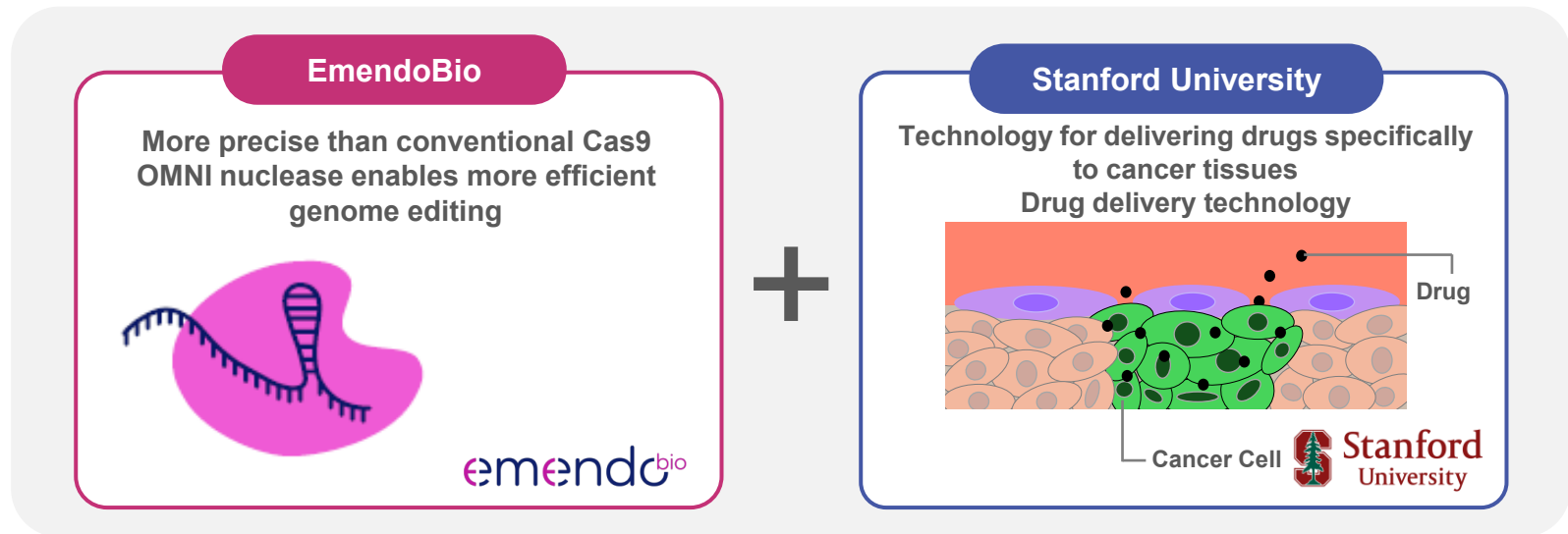
Using EmendoBio's OMNI nuclease, the company inserts the genes encoding the appropriate TCR receptors into a patient's T cells to generate TCR-T cells targeting the relevant cancer.



Joint research with Stanford University

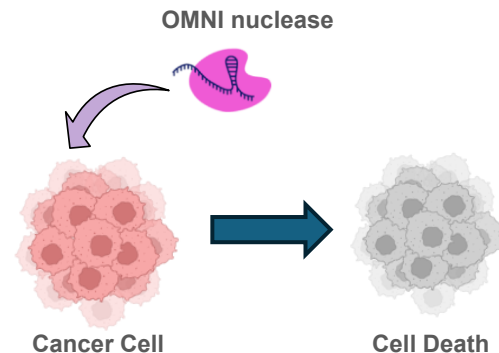
Using the OMNI nuclease developed by EmendoBio

Launch of joint research and development of a novel cancer therapy with Stanford University



Development of a novel genome editing therapy targeting breast cancer

At Stanford University, advanced research has been conducted in the development of new cancer treatments such as technologies for cancer tissue-specific drug delivery, cancer radiotherapy, and cancer immunotherapy. By using Emendo's OMNI nuclease to edit the genome specifically in cancer cells, we aim to develop a treatment method that kills only cancer cells by reducing their therapeutic resistance.



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Other Topics

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ACRL Testing Business

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EmendoBio Genome Editing Technology

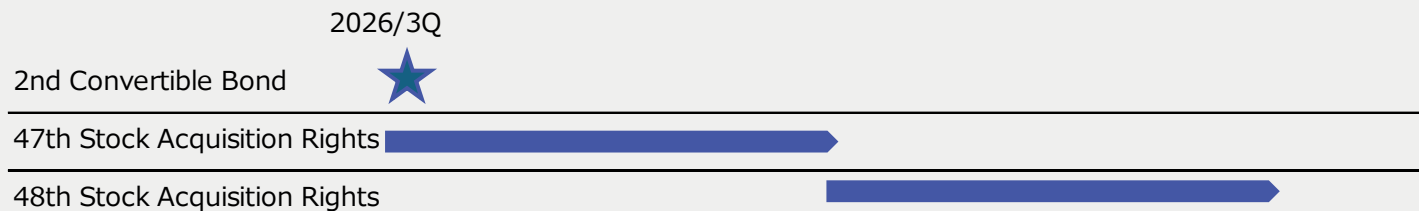
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Financing Activities

Overall Structure

- 2nd Unsecured Convertible Bond
Raising ¥2.0 billion
- 47th Stock Acquisition Rights (with Exercise Price Adjustment Provision)
Repurchase and cancellation of the remaining 46th Stock Acquisition Rights,
followed by the issuance of new Stock Acquisition Rights
Initial exercise price: ¥50 Total funding amount: approximately ¥4.0 billion
- 48th Stock Acquisition Rights
Additional issuance of Stock Acquisition Rights
Exercise price: ¥43.5 Total funding amount: approximately ¥2.5 billion

Financing Structure



Stock Acquisition Rights

- 47th Stock Acquisition Rights
 - Initial exercise price: ¥50
 - Exercise price will be adjusted to 90% of the previous day's closing price
 - Minimum exercise price: ¥25
- 48th Stock Acquisition Rights
 - Exercise price: ¥43.5

Convertible Bond

- Principal amount: ¥2 billion
- Conversion into common shares will be permitted upon completion of the exercise of the 47th Stock Acquisition Rights or upon their acquisition and cancellation.
- Conversion price: ¥43.5 per share

Subscribers to the Convertible Bond

GP Listed Company Investment Limited Partnership

Subscribers to the Stock Acquisition Rights

GP Listed Company Investment Limited Partnership

Rationale for Selecting This Financing Structure

- Secure the funds required in the near term through the convertible bond while maintaining access to medium- to long-term financing opportunities through the exercise of the stock acquisition rights.
- Entered into a business alliance agreement with Growth Partners Co., Ltd. (GP).
 - GP is expected to provide not only financing, but also management and business development support under the business alliance agreement. Through collaboration with GP, the Company aims to enhance its corporate value.

Genetic Innovation for All



<https://www.anges.co.jp/en>