COMPANY RESEARCH AND ANALYSIS REPORT

AnGes, Inc.

4563

Tokyo Stock Exchange Growth Market

5-Jun.-2026

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Summary

Preparations for the 2027 launch of HGF gene therapy products are progressing steadily

AnGes, Inc. <4563> (hereafter, also "the Company") is a biotechnology venture originating from the University of Osaka, founded in 1999. The Company's vision is to "contribute to improving the quality of life (QOL) of people worldwide by delivering innovation for diseases that still lack effective treatments, as a global leader in genetic medicine." The Company acquired EmendoBio Inc. (hereafter, "EmendoBio") as a subsidiary in 2020 to strengthen development of advanced genome editing technologies. In 2021, it launched testing services through the establishment of AnGes Clinical Research Laboratory (hereafter, "ACRL"), a clinical laboratory in Japan specializing in expanded newborn screening for rare genetic disorders.

1. Strategy for development of HGF gene therapy products

In August 2025, the Company announced a policy to seek commercialization of its core pipeline HGF gene therapy product by filing a Biologics License Application (hereafter, "BLA") with the US Food and Drug Administration (hereafter, "FDA"), based on favorable results from the late Phase II clinical trial conducted in the US. In addition, the Company entered into a contract development and manufacturing agreement with Boehringer Ingelheim Biopharmaceuticals GmbH (hereafter, "Boehringer"), its supplier of drug substances, to establish a new manufacturing framework in preparation for commercialization of the product. The current schedule calls for submission of the BLA in 2026 and commercialization in the latter half of 2027. The Company also intends to commence full-fledged sales licensing negotiations with major pharmaceutical companies after April 2026, after narrowing the list of candidates to around four companies, and aims to finalize agreements before completion of the BLA submission. According to research firms, the Company has received estimates indicating that the eligible patients for the disease in the US are approximately 500,000 annually. Assuming the product is administered to around 10% of these patients, FISCO estimates that the sales potential could exceed ¥100.0bn. In addition, the Company is reportedly examining ways to increase procurement of the drug substance to enable supply of treatments for 50,000 patients annually.

2. Status of other pipelines

Enrollment in the domestic Phase II clinical trial of NF-κB decoy oligonucleotide DNA for chronic discogenic lumbar back pain has been somewhat delayed due to the rigorous screening process for subject selection. Accordingly, enrollment is expected to be completed in the latter half of 2026, with topline data likely to be announced around the end of 2027. Subsequent development policy will depend on discussions with development partner Shionogi & Co., Ltd. <4507>.

AV-001, which the Company is jointly developing with Vasomune Therapeutics, Inc. (hereafter, "Vasomune"), is undergoing an early Phase II clinical trial in North America for acute respiratory distress syndrome (ARDS), including viral and bacterial pneumonia as target indications. The trial is expected to be completed in the first quarter of 2026, with topline data scheduled to be announced in summer 2026. The Company also decided to initiate an investigator-initiated clinical trial aimed at preventing brain injury in hemodialysis patients, with the first subject enrolled in January of the same year.

Summary

Subsidiary EmendoBio entered into a new agreement with Anocca AB (hereafter, “Anocca”) to expand the scope of application of the non-exclusive license agreement for OMNI nucleases concluded in 2024. Anocca is advancing development of TCR-T cell therapies for refractory solid tumors and is expected to begin clinical trials utilizing OMNI-A4 in 2026. The Company expects to recognize milestone income from this program. The OMNI nuclease technology is also undergoing technical evaluation by two overseas pharmaceutical companies, which may lead to new licensing agreements being signed during 2026.

3. Results trends

For FY12/25, business revenue was ¥874mn (up ¥230mn year on year (YoY)), while operating loss was ¥5,145mn (down ¥3,964mn). Growth in the number of tests conducted by ACRL contributed to the increase in business revenue. On the cost side, loss narrowed significantly due to the absence of ¥3,322mn in goodwill amortization related to EmendoBio, as well as reductions in personnel expenses and outsourcing expenses.

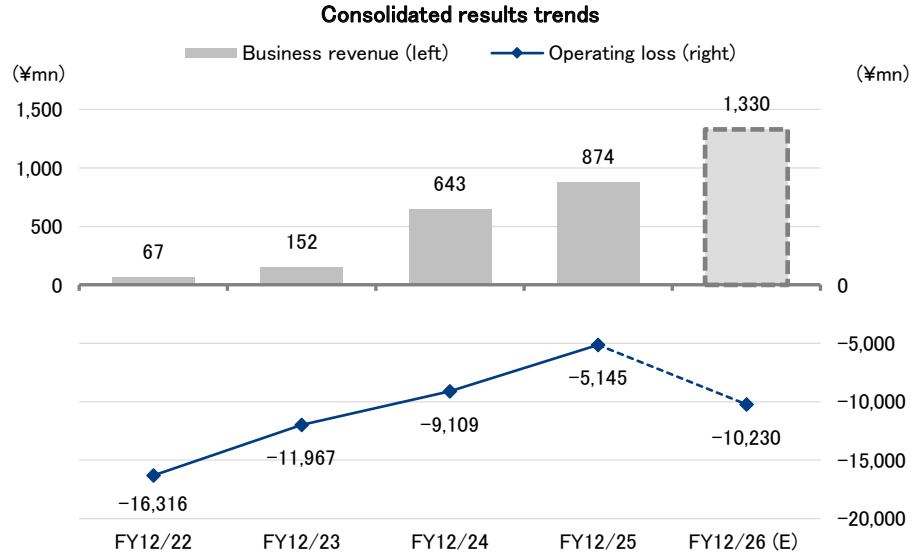
For FY12/26, the Company forecasts business revenue of ¥1,330mn (up ¥456mn YoY) and operating loss of ¥10,230mn (up ¥5,085mn), with loss expected to expand again. Business revenue is expected to increase due to growth in sales of Zokinvy, while higher research and development expenses associated with drug substance manufacturing costs for HGF gene therapy products and preparation expenses for US regulatory filings are expected to drive the expansion in loss. However, these expenses represent upfront investments aimed at generating future revenue and can therefore be viewed positively. No upfront licensing revenue related to HGF gene therapy products has been factored into the Company’s forecasts. Accordingly, if licensing agreements are signed, a meaningful upward revision to earnings may be anticipated.

As of the end of December 2025, cash and deposits totaled ¥1,882mn. However, the Company intends to procure the funds necessary for future business activities through measures including the exercise of stock acquisition rights and the issuance of privately placed bonds. The Company believes that its current corporate value (with a market capitalization of approximately ¥20.0bn) is too low relative to the potential market value of HGF gene therapy products following commercialization. Anticipating an increase in takeover risk going forward, the Company introduced anti-takeover measures in February 2026.

Key Points

- Sales potential for HGF gene therapy products exceeds ¥100bn in the US market alone
- Clinical trial results for AV-001 targeting ARDS are scheduled to be announced around summer 2026
- Development pipelines using licensed OMNI technology are expected to enter clinical trials in 2026
- The Company has established financing measures through the issuance of privately placed bonds, with anti-takeover measures also introduced

Summary



Source: Prepared by FISCO from the Company's financial results

Company profile

Biotechnology venture originating from the University of Osaka specializes in the development of genetic medicine

1. History

The Company is a biotechnology venture originating from the University of Osaka and was established in 1999 with the aim of commercializing research related to the angiogenic effects of hepatocyte growth factor (HGF) genes. For HGF gene therapy products, the Company entered into exclusive licensing agreements with Mitsubishi Tanabe Pharma Corporation <MTZPY> covering peripheral vascular disease in the US market in 2012 and the domestic market in 2015. Subsequently, in March 2019, the Company obtained conditional and time-limited manufacturing and marketing approval in Japan for patients with chronic arterial occlusive disease, and sales commenced through Mitsubishi Tanabe Pharma Corporation in September of the same year. However, based on the results of the post-marketing evaluation required under the conditional approval, which failed to reproduce results of the Phase III clinical trial, as well as favorable results from a late Phase II clinical trial conducted in the US, the Company decided to revise its development strategy from a strategic perspective, including temporarily withdrawing its application for full approval in June 2024. As a result, the Company terminated its exclusive licensing agreements with Mitsubishi Tanabe Pharma Corporation covering Japan and the US (termination dates: November 2024 for Japan and February 2025 for the US).

Among the Company's other pipelines, NF-κB decoy oligonucleotide DNA, a nucleic acid medicine, produced favorable results in a late Phase I clinical trial initiated in the US in 2018 for chronic discogenic lumbar back pain. Following these results, the Company entered into an agreement with Shionogi & Co., Ltd. in March 2023 regarding a domestic Phase II clinical trial, and commenced the trial in October of the same year. The Company also signed a domestic sales agreement in May 2022 with Eiger BioPharmaceuticals, Inc. (hereafter, "Eiger") for Zokinvy, a treatment for Hutchinson-Gilford Progeria Syndrome (HGPS), also known as infantile progeria syndrome in infants, and progeroid laminopathies (PDPL)*1. The Company obtained manufacturing and marketing approval in January 2024 and launched sales in May of the same year*2.

*1 HGPS (Hutchinson-Gilford Progeria Syndrome), also known as infantile progeria syndrome, is a highly fatal disease caused by mutations in the LMNA gene. It is characterized by severe growth impairment, scleroderma-like skin conditions, generalized lipodystrophic muscular atrophy, alopecia, skeletal abnormalities, and accelerated arteriosclerosis, with the average life expectancy reported to be 14.5 years. PDPL (processing-deficient progeroid laminopathy) is also caused by mutations in the LMNA or ZMPSTE24 genes, resulting in similar symptoms and accelerated aging. The number of HGPS and PDPL patients worldwide is estimated at approximately 600. HGPS is also designated as an intractable disease in Japan, where the number of patients is reported to be only several individuals. Annual sales per patient exceed ¥100mn based on the drug price.
*2 Following Eiger's filing for protection under Chapter 11 of the US Bankruptcy Code in April 2024, the agreement related to Zokinvy was transferred to and will continue with Sentynl Therapeutics, Inc., the successor company to the business.

Under its M&A and alliance strategy, the Company signed a co-development agreement with Vasomune in 2018 and made an investment of ¥273mn in 2023, while continuing development of AV-001 (a Tie2 receptor agonist) as a treatment candidate for ARDS. Additionally in 2018, the Company invested in MyBiotics Pharma Ltd., an Israel-based company focused on microbiome research and development. In 2022, it additionally underwrote ¥74mn in convertible bonds, which have since been written down through impairment processing. Furthermore, in 2020, the Company acquired shares of EmendoBio, which is developing treatments for rare genetic disorders using genome editing technology, and made it a subsidiary.

Apart from its pharmaceutical development business, the Company opened ACRL in April 2021 as a clinical laboratory dedicated mainly to screening newborns for rare genetic disorders. Working together with General Incorporated Association Clinical & Research Association for Rare, Intractable Diseases (hereafter, "CReARID")*, the Company launched contract testing services for optional screening tests.

* Although CReARID ended its contract services for optional screening tests at the end of March 2025, AnGes, Inc. has taken over and continues to provide the services.

2. Business features and business model

A key feature of the Company's business is that it defines gene therapy products, nucleic acid medicines, and DNA vaccines, which utilize the functions of genes, as genetic medicine, and targets intractable diseases and diseases lacking effective treatments, where clear medical needs exist and which the Company regards as part of its social mission. In addition to internally developed products, the Company also in-licenses development candidates that align with its business strategy from overseas ventures and academic research institutions, thereby strengthening its development pipeline and diversifying risk.

The business model is centered on specializing in research and development (with manufacturing outsourced to external specialized organizations) and entering into co-development agreements and exclusive licensing agreements with major pharmaceutical companies for its development candidates. Revenue is primarily generated through upfront payments, milestone payments based on development progress, and royalty income calculated as a certain percentage of product sales after commercialization. The scale and duration of clinical trials vary depending on the target disease, but it is generally said that Phase I through Phase III clinical trials take approximately three to seven years. If clinical trial results are favorable, an application for manufacturing and marketing approval is submitted to regulatory authorities. After a review period of approximately one to two years, the product is approved and launched if no issues are identified. The success rate of new drug development is low, and it is said that only about 1 in 30,000 lead compounds identified at the basic research stage ultimately reach the market as approved drugs.

In its testing services for rare genetic disorders, the Company primarily undertakes expanded newborn screening tests*1 to detect rare genetic disorders in newborns, mainly from clinics in the Tokyo metropolitan area. From 2024, it also began receiving orders through local governments. If a screening result indicates the need for further examination, genetic testing (diagnostic testing)*2 is conducted. When patients are diagnosed through screening and follow-up diagnostic testing, starting treatment at an early, pre-symptomatic stage is expected to help inhibit the progression of symptoms. The diseases covered by the testing service are rare genetic disorders outside the scope of mass screening programs conducted by local governments at public expense (covering 20 diseases), and tests are provided on a fee-based basis to individuals who wish to undergo them. Currently, ACRL is able to test for 14 diseases*3, including mucopolysaccharidosis and Fabry diseases (in male patients only), and the Company intends to expand the scope of detectable diseases on an ongoing basis.

*1 The Company provides fee-based testing services for hereditary diseases that are not included in mass screening programs conducted for all newborns at public expense.
*2 A diagnostic test used to determine whether a patient has a specific disease by checking for the presence of genetic mutations that cause the disease, when screening results suggest a possible diagnosis or when symptoms indicate a potential corresponding condition.
*3 The service covers the following diseases: mucopolysaccharidosis (types I, II, IVA, VI, and VII), Pompe disease, Fabry disease, Gaucher disease, Niemann-Pick disease type A/B, Krabbe disease, adrenoleukodystrophy, spinal muscular atrophy, severe combined immunodeficiency, and adenosine deaminase deficiency. In Tokyo, mucopolysaccharidosis (types I and II) and Pompe disease were added to the mass screening program in March 2025.

Trends in major development pipelines

HGF gene therapy products have sales potential of more than ¥100.0bn in the US market alone

The Company's main development pipeline includes HGF gene therapy products, NF-κB decoy oligonucleotide DNA, and a Tie2 receptor agonist being co-developed with its partner Vasomune.

Status of major development pipelines

Project	Region	Licensee/Partner	Indication	Development Stage
HGF gene therapy products	Japan	-	Chronic arterial occlusive disease	In June 2024, the Company withdrew its application for full approval seeking removal of conditional and time-limited marketing authorization conditions. Future development policy will be reviewed based on developments in the US program
	US	-	Chronic limb-threatening ischemia	The late Phase II clinical trial (75 cases) was completed in March 2023, and the principal investigator announced topline data at an academic conference in November 2024. Preparations are underway in the US for a marketing approval application
	Israel	Kamada Ltd.	Chronic arterial occlusive disease	Following the withdrawal of the domestic application for full approval, Kamada also withdrew its marketing authorization application
	Turkey	ER-KIM Pharmaceuticals Co., Ltd.	Chronic arterial occlusive disease	In line with the withdrawal of the domestic application for full approval, ER-KIM Pharmaceuticals Co., Ltd. also temporarily halted its application preparations
NF-κB decoy oligonucleotide DNA	US	-	Chronic discogenic lumbar back pain	A late Phase I clinical trial in the US was completed (25 cases, 2018–2021). In May 2025, the results were published in The Spine Journal, a specialist journal for spinal disorders
	Japan	Shionogi & Co., Ltd.	Chronic discogenic lumbar back pain	In Japan, the Company entered into an agreement with Shionogi & Co., Ltd. for collaboration on a Phase II clinical trial, which commenced in October 2023 (planned enrollment: 92 cases)
Tie2 receptor agonist AV-001	US	Vasomune Therapeutics, Inc.	ARDS	A joint development agreement was signed with Vasomune in July 2018, and an early Phase II clinical trial was initiated in North America in January 2022 (planned enrollment: 60 cases)

Source: Prepared by FISCO from the Company's results briefing materials

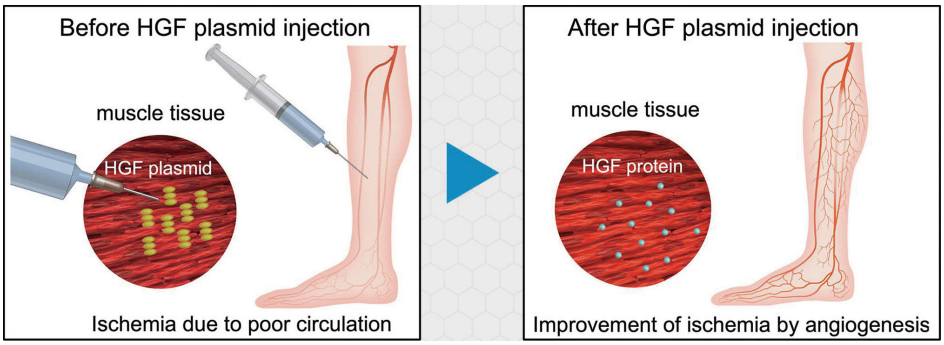
1. HGF gene therapy products

HGF gene therapy products have been developed as a treatment for patients with advanced chronic arterial occlusive disease by leveraging their angiogenic effects. Chronic arterial occlusive disease is a serious condition in which blood vessels become blocked, leading to impaired blood flow, resulting in tissue ulcers and gangrene, and in some cases ultimately requiring limb amputation. Current treatment options include catheter-based interventions and vascular bypass surgery; however, many cases are ineligible for surgery, and the development of new therapeutic approaches is therefore required.

HGF gene therapy products are administered via multiple injections around the site of the vascular occlusive to induce new blood vessel formation and restore blood flow, thereby promoting the improvement of ulcers. In Japan, the Company obtained conditional and time-limited approval in March 2019 for the indication of improvement of ulcers in chronic arterial occlusive disease in patients for whom standard drug therapy is insufficiently effective and who are not candidates for revascularization surgery. Sales of Collategene® Intramuscular Injection 4mg* commenced in September of the same year through its partner Mitsubishi Tanabe Pharma Corporation. After conducting the post-marketing approval condition evaluation, the Company submitted an application for full approval in May 2023. However, in light of the failure to replicate the results of the domestic Phase III clinical trial and positive results from a late Phase II clinical trial conducted in the US, the Company decided from a strategic standpoint to withdraw the application in June 2024 and terminate sales in Japan.

* The dosing regimen consists of intramuscular administration to the ischemic site twice at four-week intervals (4mg per dose). If symptoms persist, a third dose may be administered four weeks after the second injection (drug price: approximately ¥610,000 per 4mg vial).

HGF gene therapy-mediated angiogenesis



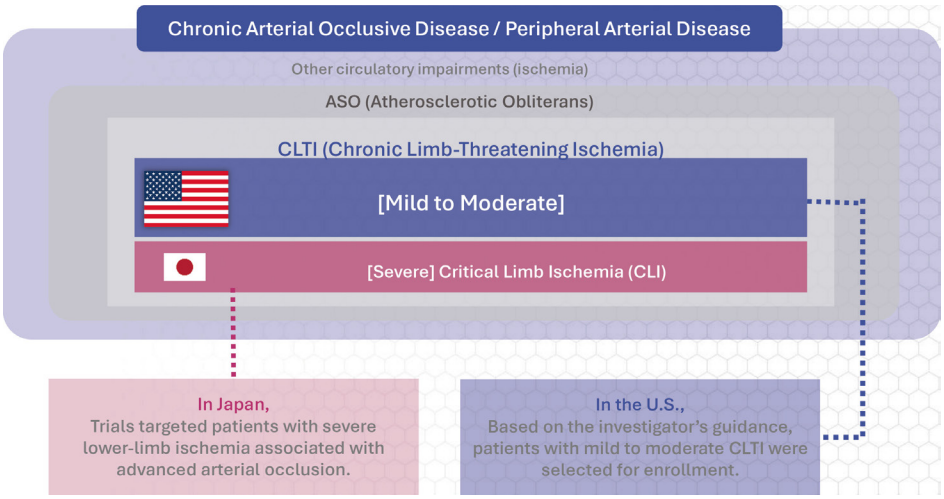
Source: The Company's results briefing materials

While developments in Japan focused on patients with severe disease, in the US, based on the revised Global Vascular Guideline* for chronic limb-threatening ischemia issued in June 2019 and proposals from the clinical investigators, the Company conducted a clinical trial targeting stage one or two patients with a lower risk of lower-limb amputation. The trial was designed based on the hypothesis proposed by the principal investigator that patients with critical limb ischemia should be treated as early as possible, similar to cancer.

* Global Vascular Guideline (hereafter, "GVG"): recommends improving patients' QOL by providing appropriate treatment management from the early stages of Chronic Limb-Threatening Ischemia (hereafter, "CLTI"). The guideline classifies clinical stages into four levels (clinical stages one to four) and outlines treatment strategies for each stage. The late Phase II clinical trial conducted in the US targeted clinical stages one and two, which carry a lower risk of lower-limb amputation. For patients at these stages, the guideline recommends that treatment of ulcers should be considered first.

Trends in major development pipelines

Disease indications in clinical trials in Japan and the US



Source: The Company's disclosure of business plans and growth potential

In the late Phase II clinical trial conducted in the US, the primary endpoints were "time to healing" and "the proportion of completely healed ulcers at six months after administration." A placebo-controlled, randomized, double-blind study was conducted in which either the HGF gene therapy product or placebo was administered four times at four-week intervals. Subjects were divided into 3 groups: 4mg per dose, 8mg per dose, and placebo, and data was collected over a 12-month observation period (a total of 75 subjects were enrolled, including allowances for dropouts). At the American Heart Association (hereafter, "AHA") meeting held in November 2024, the principal investigator presented topline data from the clinical trial, confirming that "time to healing" was significantly shortened in the treatment group compared with the placebo group. In addition to "the proportion of completely healed ulcers at 6 months after administration," efficacy versus the placebo group was also confirmed in "the proportion of completely healed ulcers at 12 months" and "the ulcer recurrence rate at 12 months."

The clinical trial results were further detailed in a paper prepared by the principal investigator and published in November 2025 in "Circulation: Cardiovascular Interventions*," a leading journal issued by the AHA. Specifically, the trial results confirmed that the median time to healing was 84 days in the treatment group versus 280 days in the placebo group (p=0.007). The proportion of completely healed ulcers at 6 months was 63.3% in the treatment group compared with 38.5% in the placebo group (p=0.053). At 12 months, the proportion of healed ulcers was 77.6% in the treatment group versus 46.2% in the placebo group (p=0.010). Based on the above results, the HGF gene therapy product was concluded to significantly shorten the time to complete ulcer healing in patients with moderate CLTI and may represent a promising non-surgical treatment option.

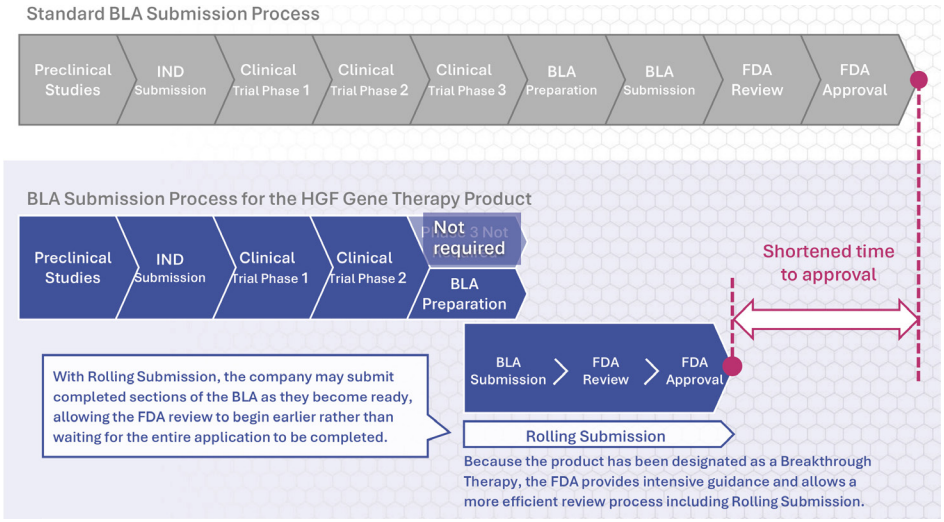
* This is a peer-reviewed journal focused on cardiovascular intervention, a field that researches and practices minimally invasive treatments for cardiac and vascular diseases using catheter-based techniques. It is frequently cited as a reference in other academic publications and is recognized as a leading journal with significant influence.

Trends in major development pipelines

In August 2025, the Company decided to complete the clinical trial and proceed with preparations for a BLA submission to the US. Following this decision, the Company entered into a contract development and manufacturing agreement with Boehringer, the contract manufacturer of the HGF gene therapy product, to establish a drug substance manufacturing framework for regulatory approval and commercialization. Until now, the drug substance had been manufactured and supplied using small-scale facilities for clinical trials; however, commercialization would require the construction of large-scale bioreactors with a capacity of around 4,000 liters, which in turn would require a certain amount of time and investment. Boehringer plans to establish Chemistry, Manufacturing, and Controls (hereafter, "CMC") related to formulation, manufacturing processes, and quality control in preparation for the planned BLA submission in 2026. The product has been designated as a Breakthrough Therapy Designation* by the FDA, allowing BLA submission documents to be filed on a rolling basis as each section becomes ready. The Company anticipates submitting the initial BLA documentation to the FDA in the second quarter of 2026, with the CMC information related to drug substance manufacturing by Boehringer expected to be submitted as the final part of the application in the first quarter of 2027. Accordingly, if development proceeds as planned, the Company could obtain marketing approval in the third quarter of 2027 and potentially launch the product within 2027.

* The Breakthrough Therapy Designation is a system introduced by the FDA to expedite the development and review of new therapies for serious or life-threatening diseases. It is granted to drug candidates that, based on clinical trial data, demonstrate the potential to provide substantial improvement over existing treatments.

BLA submission process



Source: The Company's results briefing materials

The Company plans to begin full-scale licensing negotiations with sales partners from April 2026 and aims to conclude an agreement within 2026. Initially, the Company planned to fully launch licensing activities upon publication of a detailed paper on the US clinical trial (announced in January 2026). However, the Company decided that it would be more efficient to proceed with negotiations after the March shareholders' meeting and after consolidating a substantial portion of the BLA submission documents. Although around 10 candidate companies were initially identified, the Company intends to focus negotiations on 4: 2 leading companies in diabetes therapeutics, where overlapping indications are common, and 2 major companies with strong track records in the cardiovascular area. The Company aims to conclude agreements with the support of US specialist physicians. The negotiation period is expected to be approximately six months. If the agreement is successfully concluded, the Company will receive upfront payments, milestone payments, and royalty income based on post-launch sales.

Upfront payments and milestone payments are often calculated by applying a certain percentage to peak sales. FISCO estimates that the market size for HGF gene therapy products exceeds at least ¥100bn in the US alone. The number of eligible patients in the US is estimated by a research firm at approximately 500,000 (compared with 5,000–20,000 in Japan). Of these, about 10% (50,000 patients) are assumed to use the product. This figure is then multiplied by the domestic drug price (approximately ¥610,000 per 4mg vial) and the four doses per patient. The Company is also considering expanding the procurement volume of drug substance in order to supply treatment for 50,000 patients annually. It is also suggested that if pricing is assumed to be comparable to the treatment cost of revascularization procedures, the market size could be more than four times larger. If launched in the US, the product is expected to be expanded to Japan and Europe, giving it even greater global potential, and the Company's performance is expected to grow significantly.

The results of the Phase II clinical trial for chronic discogenic lumbar back pain are expected to be announced around the end of 2027

2. NF-κB decoy oligonucleotide DNA

NF-κB decoy oligonucleotide DNA is a type of nucleic acid medicine that regulates gene function using synthetic nucleic acids. It is a specific inhibitor of a transcription factor protein (NF-κB) that induces immune and inflammatory responses in the body. NF-κB binds to specific DNA sequences in genes and activates their expression, leading to the production of proteins that cause inflammation, including pain. By introducing NF-κB decoy oligonucleotide DNA into cells, the binding between NF-κB and gene regions responsible for producing inflammatory proteins is inhibited, thereby suppressing the production of such proteins.

The domestic Phase II clinical trial of NF-κB decoy oligonucleotide DNA was initiated in October 2023 for chronic discogenic lumbar back pain*, following the conclusion of a collaboration agreement with Shionogi & Co., Ltd. in March 2023, under which the Company partially bears the cost of the clinical trial. The trial plans to enroll 92 patients in total. An initial safety test at the maximum dose of 20mg is performed in the first 2 cases, after which a comparative trial is conducted with three groups—10mg, 20mg, and placebo—each consisting of 30 patients receiving a single dose. The observation period is 12 months, and efficacy is evaluated based on changes in the Numerical Rating Scale (hereafter, "NRS"), an indicator of pain. Enrollment in the 20mg dose is currently underway, with completion of recruitment expected in the second half of 2026. Although slightly behind the initial schedule, this is due to more careful and detailed patient selection to ensure the best possible outcomes. Accordingly, the clinical trial results are anticipated to be released no earlier than around late 2027. In the event of positive results, the Company plans to pursue out-licensing, subject to discussions with Shionogi & Co., Ltd.

* Chronic discogenic lumbar back pain refers to low back pain caused by intervertebral disc disorders that persists for more than three months. It is estimated to account for approximately 40% of chronic low back pain cases. Eligible clinical trial participants are patients aged 18–75 whose NRS score for low back pain (a self-reported pain scale) is higher than their NRS score for buttock pain or lower-limb pain. The study targets patients with inadequate efficacy from conservative low back pain treatment whose NRS scores at screening and on both the administration day and the preceding day range from four to nine, indicating moderate to severe pain. In addition, patients experiencing pain in multiple locations are excluded from the study.

The results of a late Phase I clinical trial conducted in the US from 2018 ahead of the domestic clinical trial (a placebo-controlled, randomized, double-blind comparative study involving 25 patients with a 50-week observation period) were published in May 2025 in The Spine Journal*, a specialist academic journal focused on spinal disorders. The trial confirmed no safety or tolerability concerns. Regarding efficacy, the highest-dose cohort among the three dose groups (0.3mg, 3.0mg, and 10.0mg) demonstrated marked improvement in low back pain soon after administration. After one year, pain scores had improved by an average of 77% from baseline (compared with an average improvement of 40% in the placebo group). Furthermore, no cases in the highest-dose group required supplemental analgesic treatment throughout the trial period, indicating the persistence of analgesic effects. More specifically, pain almost completely disappeared in approximately half of the patients in the highest-dose group. In addition, while intervertebral disc height decreased in the placebo group, an increase was observed in the 10mg dose group, suggesting a potential morphological improvement effect on the intervertebral discs. As the clinical trial in Japan also includes a 20mg dose group exceeding the maximum dose used in the US trial, FISCO believes there is a high likelihood of obtaining favorable results.

* The Spine Journal is a leading international academic journal in the field of spinal disorders published by the North American Spine Society. It features research papers, reviews, and case reports related to spinal surgery and provides high-quality peer-reviewed articles from around the world on a biweekly basis.

In Japan, symptomatic treatments such as oral and topical medications and physical therapy are commonly used for patients with chronic discogenic lumbar back pain. However, NF-κB decoy oligonucleotide DNA is expected to provide sustained efficacy for at least one year with a single administration, thereby contributing to improved patient QOL. If successfully developed, it could become the world's first nucleic acid therapeutic for chronic discogenic lumbar back pain, and attention is focused on the clinical trial results expected to be announced around the end of 2027.

Results from the clinical trial of AV-001 for ARDS expected to be released around summer 2026

3. ARDS therapeutic drug (Tie2 receptor agonist compound)

AV-001 (a Tie2 receptor agonist)*, an ARDS therapeutic co-developed with Vasomune, has been under joint global development since 2018 as a treatment for diseases caused by vascular dysfunction, including acute respiratory failure. Believing that the drug could also be effective for patients with moderate to severe COVID-19 pneumonia, the Company began an early Phase II clinical trial in the US in January 2022. However, as the number of patients developing severe pneumonia from COVID-19 variants declined sharply, the target indication was expanded to ARDS, including viral and bacterial pneumonia such as influenza (approved by the FDA), and the clinical trial has continued under the expanded scope. Subjects are divided into three dose groups and receive either AV-001 plus standard-of-care therapy or placebo plus standard-of-care therapy, with safety, tolerability, and efficacy being evaluated.

* In 2018, the Company entered into a global co-development agreement with Vasomune for AV-001, targeting diseases caused by vascular dysfunction, including acute respiratory failure. Under the agreement, development costs and future profits are shared equally, and the Company is required to pay Vasomune upfront payments and milestone payments based on development progress. There are approximately 260,000 ARDS patients in the US alone.

As of December 2025, enrollment of the initially planned 60 cases had been completed; however, additional enrollment is being conducted to compensate for dropout cases, and all enrollment is expected to be completed in the first quarter of 2026. Topline data is expected to be announced around the summer of 2026. If favorable results are obtained, the Company intends to pursue out-licensing, although it may continue development on its own if grant funding remains available for the late Phase II clinical trial. In May 2024, AV-001 was granted Fast Track designation* by the FDA, allowing clinical trial consultations and review processes to proceed more efficiently.

* The Fast Track designation system was established to promote the development and expedite the review of new therapies for serious diseases and drugs that may address unmet medical needs.

Furthermore, an investigator-initiated clinical trial of AV-001 aimed at preventing acute ischemic brain injury in hemodialysis patients has newly commenced, with the first subject enrolled in January 2026. The trial is being conducted with funding support from the Heart and Stroke Foundation of Canada and is designed to evaluate whether AV-001 can reduce cytotoxic cerebral edema caused by hemodialysis and preserve white matter function in the brain. Should the results prove positive, the possibility of conducting a larger clinical trial will be explored. Up to 90% of patients with end-stage renal disease undergo hemodialysis, cytotoxic cerebral edema develops in roughly 70% of patients aged 55 years or older, leading to moderate to severe cognitive dysfunction and posing a significant issue in clinical practice. By targeting the Tie2/Angiopoietin-1 signaling pathway, AV-001 stabilizes vasculature and inhibits vascular leakage and inflammation, which may reduce cytotoxic cerebral edema and offer a novel treatment option for preserving brain function in patients undergoing hemodialysis.

In connection with the initiation of this investigator-initiated clinical trial, the Company entered into an agreement with Vasomune in November 2025 to expand the indications for AV-001. Under the agreement, the Company will pay US$1mn by the end of 2025 and an additional US$3mn between 2026 and 2027. However, if the product is successfully out-licensed or commercialized for this indication, the Company will also be entitled to receive a portion of the resulting proceeds.

Development status of EmendoBio

The OMNI platform's strength lies in its high level of safety among genome-editing technologies

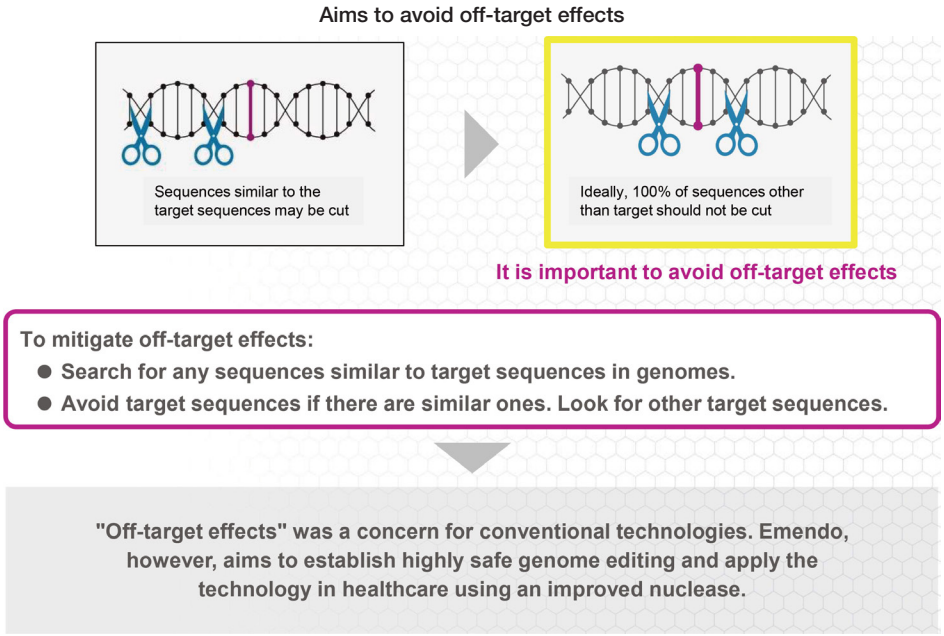
1. Features of genome editing technology and the OMNI platform

Genome editing refers to a technology that modifies target genes by using DNA-cleaving enzymes (nucleases) that cut only specific base sequences (target sequences). In 2012, the emergence of an innovation technology called CRISPR/Cas9, which enables targeted DNA sequences to be cut more quickly and easily than conventional methods, accelerated efforts within the pharmaceutical industry to develop new drugs using genome-editing technology. A therapy for sickle cell disease*, jointly developed using this technology by US-based Vertex Pharmaceuticals Inc. <VRTX> and Switzerland-based CRISPR Therapeutics <CRSP>, became the first CRISPR/Cas9-based treatment to receive approval in the UK and the US in 2023. The treatment works by applying genome-editing technology to genetically alter hematopoietic stem cells harvested from the patient and subsequently administering them back into the body through injection.

> * Sickle cell disease is a disorder in which hemoglobin, the protein in red blood cells responsible for transporting oxygen, becomes deformed due to a genetic abnormality, causing red blood cells to assume a sickle shape and become prone to destruction, resulting in anemia. As symptoms worsen, ruptured sickle-shaped red blood cells can block capillaries and cause severe pain, and prolonged progression may also lead to renal failure or heart failure. The approval covers patients aged 12 years or older who regularly suffer from sickle cell crises.

With the first approval of a therapeutic developed using CRISPR/Cas9 technology, a certain level of safety has been confirmed. However, concerns remain regarding off-target effects, in which unintended regions of the genome may be cleaved non-specifically. In contrast, the OMNI platform independently developed by EmendoBio is a system for discovering and optimizing nucleases with greater precision and safety, and is a technology for creating novel nucleases that avoid off-target effects. Patent applications have been filed for more than 250 internally developed nucleases. In the development of pharmaceuticals using genome-editing technology, not only efficacy but also safety is strongly required, and therefore FISCO believes that the OMNI platform is expected to provide a competitive advantage.

Development status of EmendoBio



Source: The Company's results briefing materials

Another distinguishing feature is its ability to perform allele-specific gene editing. This technology selectively targets and edits only the abnormal allele of a paired set of alleles, enabling treatment without damaging the normal gene. Humans possess a pair of alleles inherited from the father and mother. Hereditary diseases caused by an abnormality in one allele are referred to as "dominant inheritance (gain-of-function mutation/haploinsufficiency)," while diseases caused by abnormalities in both alleles are classified as "recessive inheritance (compound heterozygous/homozygous)" or "sex-linked inheritance (diseases in which manifestation differs by sex)." Allele-specific gene editing targets dominant inheritance disorders, which are believed to account for more than half of hereditary diseases. This means that the scope for developing genome-editing therapies using the OMNI platform is extremely broad. According to research by EmendoBio, the market size for therapies targeting genetic disorders is estimated at approximately ¥2tn in total, of which approximately ¥1.1tn could fall within the addressable area of the OMNI platform, indicating significant potential growth.

Clinical trial initiation is anticipated in 2026 for development pipelines incorporating OMNI technology at partner companies

2. Business strategy

EmendoBio implemented a business restructuring in 2024 due in part to the prolonged conflict in Israel, and currently operates with a team of approximately 20 researchers and IT engineers focused on genome-editing technology. Given its financial condition, EmendoBio is concentrating its business strategy on licensing activities for over 250 OMNI nucleases and the OMNI platform developed to date.

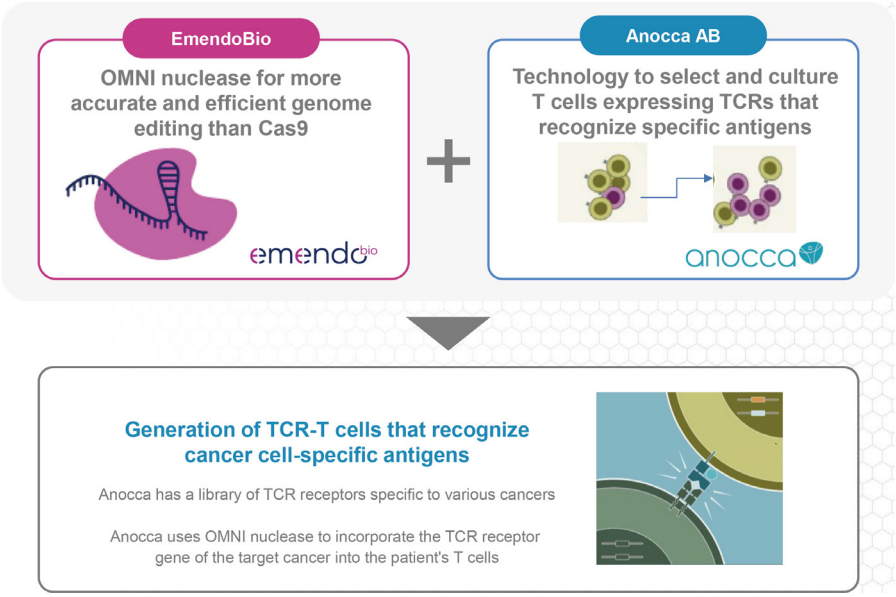
Development status of EmendoBio

Regarding licensing agreements, in March 2024, EmendoBio signed a non-exclusive license agreement with Anocca*1 for the rights to use the OMNI-A4 nuclease. Anocca is a Sweden-based company that leads the industry in the development of TCR-T cell therapy*2, a form of cancer immunotherapy. Anocca is advancing development using the OMNI-A4 nuclease to target KRAS protein mutations in refractory solid tumors. In September 2025, the Company announced that it had agreed to expand the scope of the licensing agreement. Anocca highly values the OMNI technology, and it is expected to actively utilize OMNI nucleases in its future development pipeline. Anocca plans to initiate clinical trials for a development pipeline using OMNI-A4 as early as 2026, and milestone payments are expected. Under the original agreement, the total milestone payments, including the upfront payments, were up to US$100mn, but this amount may increase following the expansion of the licensing scope. In TCR-T cell therapy, Adaptimmune Therapeutics' <ADAP> afamitresgene autoleucel (TECELRA) received its first US marketing approval in August 2024 for use in a subset of metastatic synovial sarcoma.

*1 Anocca is a biotech venture established in 2014 with more than 100 employees, primarily consisting of scientists, engineers, and software developers. Anocca possesses technology for selecting and culturing T cells that express T-cell receptors recognizing specific antigens, and has a library of TCR-T cell therapies targeting multiple cancer antigens, with more than 40 product candidates in its pipeline.

*2 TCR-T cell therapy refers to a gene-modified T-cell therapy in which lymphocytes are harvested from a patient, engineered by introducing a cancer antigen-specific T-cell receptor into the T cells, and subsequently reinfused into the same patient. Development is ongoing for use in refractory solid tumors.

TCR-T cell therapy



Source: The Company's results briefing materials

Development status of EmendoBio

Furthermore, regarding contract negotiations with other companies, a Swiss pharmaceutical company is currently conducting a technical evaluation of the OMNI platform, and if favorable results are obtained, this could lead to a licensing agreement as early as 2026. In January 2025, the Company entered into a joint research agreement with Stanford University in the US to develop novel cancer therapies using genome-editing technology. The research targets the development of a new treatment for hereditary refractory breast cancer by integrating Stanford University's intracellular drug delivery technology with OMNI nucleases from EmendoBio to enable cancer cell-specific genome editing, thereby reducing therapy resistance and selectively inducing cancer cell death. The research is expected to run for approximately 2 years with a budget of around US$1.30mn. The research results are scheduled to be published in a paper around the end of 2026. In addition, to share the intellectual property of the developed technology with Stanford University, the Company plans to establish a small laboratory near the university. Going forward, the development of OMNI nucleases will require greater expertise in computer science, and Stanford University has a large number of highly capable engineers in this area. The Company is also considering recruiting these talents and potentially relocating its research and development base to the US in the future.

Status of ACRL initiatives

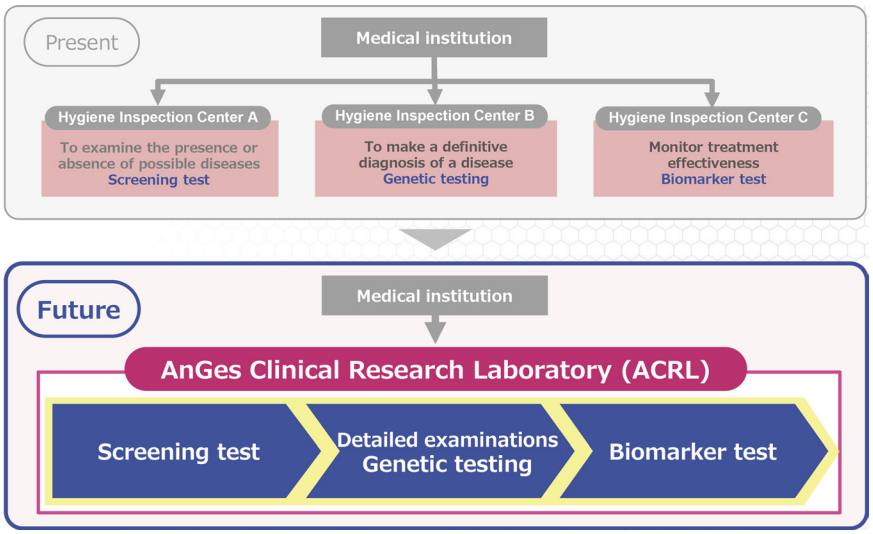
Expanding from screening tests to diagnostic and biomarker testing

The expanded newborn screening program for rare genetic disorders, which began in July 2021, has grown at approximately a double-digit growth rate, rising from around 10,000 tests in FY12/22 to approximately 90,000 tests in FY12/25. This increase was driven by the addition of testing services from CReARID, as well as the commencement of testing contracts from local governments (or related organizations), including Gunma Prefecture and Okinawa Prefecture, from August 2024 onward. From 2025, the Company also began receiving testing orders from Nagano Prefecture. In addition, following the termination of testing services by CReARID at the end of March 2025, the Company began receiving tests directly from clinics, resulting in an increase in the unit price per test. However, as the processing capacity of testing equipment and human resources has reached its upper limit, growth is expected to be limited to a slight increase in FY12/26. Regarding capacity expansion investment, the Company plans to allocate capital with the commercialization of HGF gene therapy products as its top management priority, and therefore will determine the timing of such investment after assessing its financial condition.

As part of its efforts to expand its testing business, the Company began providing genetic testing (diagnostic testing) for rare genetic disorders in May 2024. Furthermore, in September 2025, the Company began providing biomarker testing for mucopolysaccharidosis, including secondary screening, follow-up observation, and monitoring of treatment efficacy, thereby establishing a system capable of offering one-stop testing services for rare genetic disorders. Traditionally, no single laboratory has performed all of these tests, requiring medical institutions to outsource to multiple laboratories, which has been time-consuming. The use of the Company's laboratory therefore improves convenience. Although the number of confirmatory tests and biomarker tests is significantly smaller and therefore has only a limited direct impact on earnings, conducting a greater number of tests for rare genetic disorders increases opportunities to identify new therapeutic candidates, and the Company will continue to focus on this business.

Status of ACRL initiatives

Offers one-stop testing services for rare genetic disorders



Source: The Company's results briefing materials

Results trends

Losses for FY12/25 were significantly reduced due to lower expenses related to EmendoBio

1. Overview of FY12/25 results

For FY12/25, business revenue was ¥874mn (up ¥230mn YoY), operating loss was ¥5,145mn (down ¥3,964mn), ordinary loss was ¥5,288mn (down ¥2,249mn), and net loss attributable to owners of parent was ¥5,123mn (down ¥23,005mn).

Consolidated results for FY12/25

(¥mn)

	FY12/24 Results	FY12/25 Revised plan*	FY12/25 Results	Variance from plan	YoY change	Key factors (Figures in parentheses indicate YoY change)
Business revenue	643	880	874	-5	230	Testing fee income up ¥242mn, Zokinvy up ¥58mn, and R&D business revenue down ¥59mn
Cost of sales	395	-	553	-	157	Testing costs of sales up ¥100mn, while Zokinvy product procurement cost up ¥65mn
R&D expenses	3,783	-	3,553	-	-230	Research materials costs down ¥526mn, while outsourcing expenses up ¥325mn
SG&A expenses	5,573	-	1,912	-	-3,661	Amortization of goodwill down ¥3,322mn, compensation related to EmendoBio down ¥201mn, and fees related to EmendoBio down ¥140mn
Operating profit/loss	-9,109	-6,270	-5,145	1,124	3,964	
Ordinary profit/loss	-7,537	-6,290	-5,288	1,001	2,249	Foreign exchange losses down ¥1,812mn
Special profit/loss	-20,105	-	52	-	20,158	Impairment loss on EmendoBio's goodwill and right-of-use assets of ¥20,048mn
Profit/loss attributable to owners of parent	-28,128	-6,320	-5,123	1,196	23,005	

* Revised plan as of October 27, 2025
Source: Prepared by FISCO from the Company's financial results and results briefing materials

Business revenue decreased due to a ¥59mn decline in R&D business revenue in the previous fiscal year, which had included upfront payments received from Anocca, as well as the loss of ¥11mn in sales from Collategene. However, revenue increased as sales of Zokinvy rose by ¥58mn to ¥302mn and fee income from expanded newborn screening tests for rare genetic disorders increased by ¥242mn to ¥554mn, resulting in higher overall revenue.

Cost of sales increased by ¥157mn YoY to ¥553mn. This was mainly due to a ¥65mn increase in cost of goods purchased for Zokinvy and a ¥100mn increase in cost of sales associated with higher screening test fee income. The increase in Zokinvy procurement costs exceeded the revenue growth as the Company increased purchasing volumes in the fourth quarter to prepare for higher sales from 2026 onward. Purchases are settled in yen and are therefore not affected by foreign exchange fluctuations.

R&D expenses declined by ¥230mn YoY to ¥3,553mn. Outsourcing expenses increased by ¥325mn due to higher development costs in the US and expenses related to regulatory submission preparation for the HGF gene therapy product, while research materials expenses decreased by ¥526mn as losses on inventory disposal due to expiration and inventory valuation losses for Collategene, recorded in the previous fiscal year, were no longer incurred. SG&A expenses decreased by ¥3,661mn to ¥1,912mn. As a result of the full impairment of goodwill associated with EmendoBio recorded at the end of the prior fiscal year, goodwill amortization of ¥3,322mn was no longer incurred. Furthermore, personnel-related costs declined by ¥201mn due to a decrease in staffing at EmendoBio. Additionally, payment fees decreased by ¥140mn due to lower compensation paid to lawyers, consultants, and other service providers at EmendoBio.

Non-operating income deteriorated by ¥1,714mn YoY. This was mainly due to the recording of a foreign exchange loss of ¥220mn (compared with a foreign exchange gain of ¥1,591mn in the previous fiscal year) resulting from the year-end revaluation* of a US dollar-denominated loan of approximately US$100mn extended to EmendoBio. Furthermore, the significant narrowing of losses was driven by the elimination of the ¥20,048mn impairment loss on goodwill and right-of-use assets related to EmendoBio that had been recorded as an extraordinary loss in the prior year.

* The exchange rate at the end of December 2024 was ¥157 per US dollar, compared with ¥156 per US dollar at the end of December 2025.

Losses for FY12/26 are expected to expand due to the upfront expenses associated with the commercialization of the HGF gene therapy product

2. FY12/26 forecasts

For FY12/26, business revenue is projected to be ¥1,330mn (up ¥456mn YoY), operating loss is expected to be ¥10,230mn (up ¥5,085mn), ordinary loss is forecast at ¥10,240mn (up ¥4,952mn), and net loss attributable to owners of parent is planned at ¥10,250mn (up ¥5,127mn).

Consolidated forecast for FY12/26

(¥mn)

	FY12/25 Results	FY12/26 Company plan	YoY change
Business revenue	874	1,330	456
Operating loss	-5,145	-10,230	-5,085
Ordinary loss	-5,288	-10,240	-4,952
Loss attributable to owners of parent	-5,123	-10,250	-5,127

Source: Prepared by FISCO from the Company's financial results and results briefing materials

Business revenue is expected to increase mainly due to Zokinvy sales rising 1.5-fold YoY as the number of treated patients increases, as well as the recognition of milestone payments associated with the entry of Anocca's development pipeline into clinical trials. Fee income from expanded newborn screening tests is expected to increase only slightly due to capacity constraints.

On the cost side, SG&A expenses are expected to remain at a level comparable to the previous fiscal year. R&D expenses are projected to increase by approximately ¥5.5bn, mainly due to active pharmaceutical ingredient manufacturing costs for the HGF gene therapy product and regulatory submission preparation costs in the US, which will contribute to a widening of losses. However, these expenses are positioned as upfront investments to generate future revenue and are viewed as forward-looking expenditures. The upfront payment from a licensing agreement for the HGF gene therapy product has not been factored into the plan, and if such an agreement is concluded, a corresponding upward revision could be expected.

Through the issuance of private placement bonds, the Company has secured stable financing and has also implemented takeover defense measures

3. Financial position

As of the end of FY12/25, total assets increased by ¥737mn from the end of the previous fiscal year to ¥5,405mn. Within current assets, cash and deposits increased by ¥174mn to ¥1,882mn due to the exercise of stock acquisition rights through a third-party allotment. In addition, raw materials and supplies increased by ¥308mn due to purchases of active pharmaceutical ingredients for the HGF gene therapy product, and advance payments increased by ¥292mn due to prepaid manufacturing outsourcing costs for the active pharmaceutical ingredients. Within non-current assets, property, plant, and equipment decreased by ¥36mn, investment securities decreased by ¥23mn, and deferred tax assets decreased by ¥61mn.

Total liabilities decreased by ¥182mn from the end of the previous fiscal year to ¥2,329mn. Accounts payable increased by ¥235mn due to inventory purchases. On the other hand, lease liabilities decreased by ¥218mn following partial termination of a lease agreement for office premises related to EmendoBio, while income taxes payable decreased by ¥98mn and other accounts payable decreased by ¥73mn. Total net assets increased by ¥919mn from the end of the previous fiscal year to ¥3,076mn. Due to the exercise of stock acquisition rights, share capital increased by ¥2,972mn and capital surplus increased by ¥2,973mn. On the other hand, retained earnings decreased by ¥5,123mn due to the recording of net loss attributable to owners of parent.

As the Company is still in the development stage, it is likely to continue posting losses until the HGF gene therapy product is launched. Accordingly, the Company plans to secure funding for its near-term business operations through the equity market. In November 2025, it issued the 46th series of stock acquisition rights through a third-party allotment. This corresponds to 96,466 thousand shares, with a floor exercise price set at ¥40. Assuming full exercise at the initial exercise price of ¥72, total funds raised would reach ¥6,921mn, to be allocated primarily to global R&D expenses aimed at maximizing product value, including preparation for regulatory submission of the HGF gene therapy product in the US. However, given the weak share price level, progress in the exercise of these rights has been sluggish.

With upfront expenses for the commercialization of the HGF gene therapy product expected to rise in 2026, the Company has announced a plan to issue private placement bonds in several tranches to ensure stable financing, up to a maximum of ¥2,737mn (with Cantor Fitzgerald Europe, the same counterparty as the 46th series of stock acquisition rights, acting as the investor). In February 2026, the Company issued its first tranche of bonds and raised ¥700mn in funding. For future tranches, the payment date will be set five business days after the full redemption of the immediately preceding bonds. Proceeds from the exercise of the 46th series of stock acquisition rights will be used to finance the redemption of the private placement bonds. Accordingly, if the share price falls below 120% of the floor exercise price of the stock acquisition rights, new bond issuance cannot be made, and issuance may only resume if the share price remains at or above 120% for 5 consecutive business days thereafter. While the conclusion of a major licensing agreement in 2026 could substantially ease financial pressure, in its absence the Company will need to continue relying on equity market funding, and thus future licensing negotiations will be closely watched.

The Company considers its current enterprise value (market capitalization of approximately ¥20.0bn) to be too low relative to the potential market value of the HGF gene therapy product upon commercialization, and anticipates an increasing risk of takeover. Accordingly, it introduced takeover defense measures (a free allocation of stock acquisition rights) in February 2026.

Consolidated balance sheet

(¥mn)

	FY12/22	FY12/23	FY12/24	FY12/25	Changes
Current assets	12,896	5,921	3,542	4,386	843
Cash and deposits	11,035	4,160	1,707	1,882	174
Non-current assets	25,924	22,971	1,125	1,019	-106
Goodwill	23,254	21,746	-	-	-
Total assets	38,820	28,892	4,668	5,405	737
Total liabilities	8,395	2,789	2,512	2,329	-182
Advances received	5,764	637	639	641	1
Total net assets	30,425	26,103	2,156	3,076	919
<Management indicators>					
Equity ratio	78.1%	90.0%	44.0%	55.2%	11.2pp

Source: Prepared by FISCO from the Company's financial results

Breakdown of the use of funds raised from the 46th series of stock acquisition rights

Use of funds	Amount	Expected timing of expenditure
R&D expenses to maximize the global product value of the HGF gene therapy drug	¥3,087mn*	December 2025–November 2027
Expenses for expanding the testing outsourcing business of ACRL	¥590mn	December 2025–November 2027
Expenses related to the relocation of EmendoBio's R&D site	¥1,000mn	December 2025–November 2027
Working capital, including other R&D expenses	¥2,093mn	December 2025–November 2027

* To ensure more structured fundraising, the scheme was modified to raise around ¥2.7bn via private placement bonds, while repayment of the bonds will be financed through the exercise of stock acquisition rights

Source: Prepared by FISCO from IR news

Future growth strategy

Aims to become a global leader in gene therapeutics

The Company has significantly advanced the development of its lead product, the HGF gene therapy product, in the US and decided to proceed with preparations for a BLA submission. In light of this milestone, it revised its corporate philosophy and redefined its mission, vision, and values.

Specifically, the Company defined its mission as focusing on the development of gene therapeutics leveraging the power of genes and research and development of next-generation technologies such as genome editing, with the aim of providing treatment opportunities to all patients suffering from rare and intractable diseases. As its vision, the Company aims to become a global leader in gene therapeutics by driving the world forward in gene medicine and genome editing, globally deploying multiple innovative therapies and contributing to improving the QOL of people worldwide. To realize this vision, the Company defined its values as maintaining a spirit of challenge without fear of change and valuing its network with all stakeholders, while continuously incorporating cutting-edge research findings and ideas, and pursuing the creation of new technologies and product value with the highest ethical standards and a strong sense of urgency.

The Company seeks to drive revenue growth and improve corporate value by reinforcing organizational capabilities and talent development for global expansion, as well as deepening and broadening its platform technologies, while pursuing initiatives such as maximizing the value of its HGF gene therapy product, continuously expanding its pipeline, accelerating global development focused on the US and Europe, and strengthening its approach to rare genetic disorders, including its diagnostics business. By conducting testing in the field of rare genetic disorders, the Company aims to identify new drug candidates in this disease area and create a virtuous cycle in which therapeutics are developed using EmendoBio's OMNI platform. The Company believes that establishing such a cycle will bring it closer to achieving its vision of becoming a "global leader in gene therapeutics."

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