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# Financial Results for the Fiscal Year Ended September 30, 2025 [Japanese GAAP] (Non-consolidated)



November 12, 2025

Company name: Kringle Pharma, Inc.

Stock exchange listing: Tokyo Stock Exchange
URL: https://www.kringle-pharma.com/en/

Representative: Kiichi Adachi, President & CEO

Contact: Koichi Murakami, Member of the Board, Director of Corporate Planning Management

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Scheduled date of the Annual General Meeting of Shareholders: December 23, 2025

Scheduled date of commencing dividend payments: —

Scheduled date of filing securities report: December 19, 2025

80

Availability of supplementary explanatory materials on financial results: Available

15.6

Schedule of financial results briefing session: Scheduled (for institutional investors, analysts, and individual investors)

(Amounts of less than one million yen are rounded down.)

(756)

# 1. Financial Results for the Fiscal Year Ended September 30, 2025 (October 1, 2024 - September 30, 2025)

(817)

(1) Operating Results (% indicates changes from the previous corresponding period.) Ordinary profit Net sales Operating profit Profit Fiscal year ended Million yen Million yen Million yen Million yen (9.8)(909)September 30, 2025 72 (914)(916)

	Basic earnings per share	Diluted earnings per share	Return on equity	Ordinary profit to total assets	Operating profit to net sales
Fiscal year ended	Yen	Yen	%	%	%
September 30, 2025	(133.92)	_	(54.4)	(37.8)	_
September 30, 2024	(118.21)	_	(36.9)	(28.1)	_

Reference: Equity earnings (losses) of affiliates:

Fiscal year ended September 30, 2025: ¥ — million

Fiscal year ended September 30, 2024: ¥ — million

(754)

Note: Although potential shares existed, diluted earnings per share are not shown, as a net loss per share was recorded.

## (2) Financial Position

September 30, 2024

	Total assets	Net assets	Equity ratio	Net assets per share
As of	Million yen	Million yen	%	Yen
September 30, 2025	2,079	1,309	61.5	182.30
September 30, 2024	2,757	2,108	75.8	306.87

Reference: Equity: As of September 30, 2025: ¥1,279 million As of September 30, 2024: ¥2,089 million

# (3) Cash Flows

. /				
	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at end of period
Fiscal year ended	Million yen	Million yen	Million yen	Million yen
September 30, 2025	(755)	(154)	84	991
September 30, 2024	(661)	(121)	838	1,816

# 2. Dividends

2. Dividends								
		Ar	nual divider	nds		Total	Dividend	Dividends to net assets
	1st quarter- end	2nd quarter- end	3rd quarter- end	Year-end	Total	dividends (Annual)	payout ratio	
	Yen	Yen	Yen	Yen	Yen	Million yen	%	%
Fiscal year ended September 30, 2024	_	0.00	_	0.00	0.00	-	_	_
Fiscal year ended September 30, 2025	_	0.00	_	0.00	0.00	-	_	-
Fiscal year ending September 30, 2026 (Forecast)	_	0.00	ı	0.00	0.00		_	

#### 3. Financial Results Forecast for the Fiscal Year Ending September 30, 2026 (October 1, 2025 - September 30, 2026)

(% indicates changes from the previous corresponding period.)

	Net sales		Operating profit Ordinary profi		Ordinary profit	Profit			Basic earnings per share
	Million yen	%	Million yen	%	Million yen %	6	Million yen	%	Yen
Full year	72	(0.3)	(1,172)	_	(1,172) -	-	(1,173)	_	(167.21)

#### \* Notes:

- (1) Changes in accounting policies, changes in accounting estimates and retrospective restatement
  - 1) Changes in accounting policies due to the revision of accounting standards: None
  - 2) Changes in accounting policies other than 1) above: None
  - 3) Changes in accounting estimates: None
  - 4) Retrospective restatement: None
- (2) Total number of issued and outstanding shares (common shares)
  - 1) Total number of issued and outstanding shares at the end of the period (including treasury shares):

As of September 30, 2025: 7,018,200 shares As of September 30, 2024: 6,810,700 shares

2) Total number of treasury shares at the end of the period:

As of September 30, 2025: 183 shares As of September 30, 2024: 136 shares

3) Average number of shares during the period:

Fiscal year ended September 30, 2025: 6,841,997 shares Fiscal year ended September 30, 2024: 6,399,270 shares

## \* Explanation of the proper use of financial results forecast and other notes

The earnings forecasts and other forward-looking statements herein are based on information currently available to the Company and certain assumptions deemed reasonable at the time of the release of these materials. These statements are not guarantees of future performance. Actual results may differ significantly from these forecasts due to various factors. Please refer to "1. Overview of Financial Results (4) Outlook" on page 7 of the Attachments for the conditions on which financial results forecasts are based and the notes on the use of these forecasts.

<sup>\*</sup> These financial results are outside the scope of review by certified public accountants or an audit firm.

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### 1. Overview of Financial Results

## (1) Explanation of Operating Results

The forward-looking statements herein are based on the judgments of Kringle Pharma, Inc. (the "Company") as of the end of the fiscal year under review.

In the Japanese pharmaceutical market, generic substitution increased in face of rising medical costs associated with population aging and drug prices declined significantly due to "off-year" NHI price revisions. Meanwhile, higher new drug development costs, reflecting the growing scale of clinical trials, accelerated alliances and M&As between pharmaceutical companies in Japan and overseas looking to expand their corporate scale. Companies focused their R&D efforts on priority therapeutic areas and actively sought in-licensing opportunities outside their organization.

In the development of new drugs, the target is shifting from so-called "blockbuster drugs," which have a large number of potential patients and can generate large, stable future profits, to drugs that can provide effective treatment to specific patient groups. Biotech companies are said to assume a greater role because they usually concentrate their resources on a certain specific field and make decisions quickly. In response to these trends, the Japanese government, primarily led by central ministries including the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Economy, Trade and Industry (METI), has launched the Medical Innovation Support Office (MEDISO) and compiled the "Ito Review 2.0: Biomedical Edition" as part of its efforts to proactively support Japan-based biotech companies. The Conditional Early Approval System and the SAKIGAKE Designation System for pioneering drugs have been legislated in order to promote drug discovery in Japan.

Amidst the above business environment, the Company continued to focus its managerial resources on the recombinant human hepatocyte growth factor (HGF) protein and developed the business activities outlined below, in the belief that development of recombinant human HGF protein (development code: KP-100) will lead to therapeutic innovation, creating business opportunities and maximizing the value of the Company.

#### 1. Drug development activities

#### (a) Acute spinal cord injury (SCI)

The Company conducted a Phase I/II clinical trial with Professor Masaya Nakamura of the Department of Orthopaedic Surgery, Keio University School of Medicine as a coordinating investigator and obtained results that confirmed the safety and indicated the efficacy of the drug. The Company designed the Phase III clinical trial to verify the proof of concept (POC; a preliminary evidence of efficacy detected in humans with a new drug candidate under development) obtained in the Phase I/II clinical trial. On June 9, 2020, the Company submitted a clinical trial notification for the Phase III study to the Pharmaceuticals and Medical Devices Agency (PMDA).

In July 2020, the Company started the Phase III study at Spinal Injuries Center, Hokkaido Spinal Cord Injury Center, and Murayama Medical Center. A total of five medical facilities, with the addition of Japanese Red Cross Kobe Hospital and Aijinkai Rehabilitation Hospital in March 2021, which had conducted the Phase III clinical trial completed enrolling the last patients in April 2023 and the final follow-up for the last patient in October 2023. The Company received topline results of the Phase III clinical trial in February 2024, and was in the process of discussions with PMDA based on the results of the trial, with a view toward applying for approval to manufacture and market the drug in Japan. Based on the insights of PMDA gained through past discussions, the Company decided in July 2025 to conduct an additional study to verify the efficacy of the drug. The Company plans to propose a study with a high probability of success based on insights gained through the Phase I/II and the Phase III clinical trial conducted previously, and to file an application for approval upon obtaining the additional data on efficacy. Additionally, the Company issued share acquisition rights in August 2025, and decided to apply some of the proceeds to fund the additional clinical trial.

In the meantime, the Company started a preliminary consultation with the U.S. Food and Drug Agency (FDA) in September 2023 in preparation for clinical development in the U.S. and received a response from the FDA in November 2023 in relation to the meeting for Pre-Investigational New Drug (Pre-IND) application. The Company then established a collaborative network of key opinion leaders (KOLs) in North America and prepared for IND submission\*. In June 2025, the Company received Orphan Drug Designation for the drug from the FDA.

### \* Clinical trial application filed with the U.S. Food and Drug Administration (FDA)

In order to submit marketing authorization application for the treatment of acute SCI, the Company is also conducting various tests related to the process of manufacturing recombinant human HGF. Trial manufacturing (process validation) of the drug substance using the same process as commercial manufacturing, as required for the submission, was completed in the fiscal year ended September 30, 2022. Process validation for manufacturing of the drug product was also completed in the fiscal year ended September 2023. In November 2024, the Company filed an application with the Osaka Prefectural Government for Type 1 Pharmaceuticals Manufacturing and Sales Business licenses needed for making applications for manufacturing and marketing approval and received the licenses on January 7, 2025. However, it decided to give them back for now. It will continue efforts to develop a treatment of acute SCI. As soon as there arises a prospect of its applications for manufacturing and marketing approval, it will again file an application with the Osaka Prefectural Government for the same licenses.

For the purpose of identifying more effective administration methods and timing with recombinant human HGF for SCI, the Company launched a joint research program with Keio University School of Medicine in February 2021. In this joint research program, the transplantation of human induced iPS cell-derived neural stem/progenitor cells (hiPSC-NS/PC) owned by Keio University, combined with the scaffold-mediated delivery of HGF developed by the Company, demonstrated improvement in recovery of motor function in animal model of chronic complete spinal cord injury. In March 2022, Keio University and the Company jointly filed a patent application, followed by the filing of an application claiming priority based on the said patent application in March 2023. Furthermore, confirming that HGF administration in the acute phase, followed by hiPSC-NS/PC transplantation in the sub-acute phase, significantly improved motor function in animal models of severe SCI compared to each single treatment group, Keio University and the Company jointly filed a second patent application in September 2022, and a priority claim based on this patent application in September 2023. As monotherapy of both HGF and hiPSC-NS/PCs already has advanced to clinical trials in humans, a next-generation regenerative therapy combining the HGF and iPS cell technologies is expected to be put into clinical use before long for the treatment of acute and sub-acute SCI.

In December 2021, the Company's patent was issued in Europe for an HGF preparation suitable for treatment of nervous diseases. It covers the Company's proprietary drug formulation used in clinical trials for acute spinal cord injury, amyotrophic lateral sclerosis and vocal fold scarring, being the basis of expanding the target indications for HGF treatment. The patent was already granted in the US, Japan, Canada and Korea, and adding Europe further created a favorable intellectual property environment for the Company to develop HGF drug business worldwide.

## (b) Vocal fold scarring (VFS)

VFS is a condition in which vocal fold mucosa hardens and degenerates due to the formation of scar tissues (fibrosis). The investigator-initiated Phase I/II clinical trial confirmed the safety of intracordal administration of the recombinant human HGF and also detected signals of efficacy in some patients showing functional recovery of the vocal cord (J Tissue Eng Regen Med. 2018. 12:1031-1038.). Following a preliminary consultation with PMDA in July 2019 and subsequent discussions with Kyoto Prefectural University of Medicine, the Company submitted a clinical trial application for a Phase III study (placebo-controlled, double-blind trial) in October 2022 which was then accepted by PMDA. The Company then began a clinical trial at University Hospital, Kyoto Prefectural University of Medicine, and the first subject was enrolled in January 2023. In May 2023, Kurume University Hospital, Tohoku University Hospital, Kawasaki Medical School Hospital and Nihon University Hospital were added as medical institutions for carrying out clinical trials. In May 2024, Sanno Medical Center was added, followed by Fujita Health University Hospital and Fukuoka Sanno Hospital, both of which were added in January 2025. As a result, case registration is currently moving forward at a total of eight facilities.

In order to raise funds to finance clinical trial expenses, manufacture the investigational drugs, and develop a commercial formulation, the Company issued share acquisition rights in November 2021. By July 2022, all of these rights had been exercised. In addition, the Company has been utilizing public funds since April 2022, with its VFS development being selected for the Cyclic Innovation for Clinical Empowerment (CiCLE) project operated by the Japan Agency for Medical Research and Development (AMED). Furthermore, the Company issued share acquisition

rights in August 2025 for the purpose of partially financing the manufacture and development of a commercial formulation for VFS.

### (c) Amyotrophic lateral sclerosis (ALS)

A phase II clinical trial (placebo-controlled, double-blind trial) was conducted at Tohoku University Hospital and Osaka University Hospital as an investigator-initiated trial that started in May 2016, led by Professor Masashi Aoki of the Department of Neurology, Tohoku University. In November 2020, the enrollment of patients was completed, and the final follow-up for the last patient was completed in December 2021. Subsequent data analysis at Tohoku University has shown no statistically significant differences between the active and placebo groups for the primary and secondary endpoints. On the other hand, there were cases in which progression was slow in the active drug group, suggesting that more detailed analysis is required to interpret the results of this study. Regarding safety, the incidence of adverse events was similar between the active drug group and the placebo group, confirming tolerability. In April 2024, the Company and Tohoku University signed a collaborative research agreement for biomarker testing of specimens as additional analysis for this phase II clinical trial. This collaboration is expected to provide important information for the design of the next clinical trial, including the identification of a patient population in which efficacy signals can be readily detected.

### (d) Supply of drug substance to Claris Biotherapeutics, Inc.

The Company concluded a license and supply agreement with Claris Biotherapeutics, Inc. (Claris) of the U.S. in April 2020 to supply HGF drug substance for clinical development by Claris to treat ophthalmologic diseases in the U.S. In the fiscal year under review, the Company did not supply HGF drug substance to Claris. Claris filed an Investigational New Drug (IND) application in May 2021 to initiate a Phase I/II clinical trial for neurotrophic keratitis utilizing the various preclinical and clinical information related to HGF provided by the Company, and the first patient received treatment in August 2021. With this developmental milestone, the Company now receives a fixed annual technology access fee (royalty income), and recorded the fee for the applicable period in net sales. To initiate the clinical trial in Canada as well, Claris filed a clinical trial application to Health Canada in July 2022, which was approved. Patient enrollment for the clinical trial both in the U.S. and Canada has been completed, and clinical data analysis is currently underway. Claris is concurrently implementing Phase I studies for limbal stem cell deficiency and corneal scars.

Furthermore, the Company formed a business alliance with Claris in September 2023 to improve the efficiency of the manufacturing method for recombinant human HGF. The purpose of the alliance is to meet growing global demand in the future and to achieve stable worldwide supply of recombinant human HGF.

## (e) Other collaborative research

In July 2022, the Company signed a collaborative research agreement with Kyoto University focused on applied research using HGF to create regenerative medicine products. The goal of this collaboration is to apply biomaterial technology to conduct exploratory research on optimal and effective next-generation treatments for target diseases, and to expand indications for KP-100 to other intractable diseases.

In April 2024, the Company signed a collaborative research agreement with Gifu University focused on applied research using HGF to treat idiopathic osteonecrosis of the femoral head. HGF is involved in both angiogenesis and bone regeneration, and has potential as a new therapeutic agent for this intractable disease for which there are no existing drugs.

In June 2024, the Company signed a collaborative research agreement with Kanazawa University focused on applied research using HGF to treat idiopathic pulmonary fibrosis. The Company is currently conducting a phase III clinical trial in Japan for the treatment of vocal fold scar, one of the fibrotic diseases. If we succeed in developing an HGF protein drug for the treatment of vocal fold scar, it will lead to the possibility of expanding the indication to other chronic diseases caused by fibrosis. Based on the findings of this collaboration, the Company will actively consider expanding the indication to pulmonary fibrosis as the next target in fibrotic diseases.

In November 2024, the Company made a collaborative research agreement with Keio University focused on the search for a new acute-phase biomarker that predicts spontaneous recovery after spinal cord damage. Currently, the Company is preparing to make an application for approval of manufacturing and marketing recombinant human HGF for acute SCI. When a biomarker is discovered through the collaborative research and becomes available for use in determining treatment efficacy, predicting degrees of spontaneous recovery, etc. from acute SCI, it is expected to lead to better treatment for SCI subjects.

In June 2025, the Company signed a collaborative research agreement with Kobe University focused on applied research using HGF to treat Peyronie's disease, a condition in which fibrous scar tissue forms in the deeper tissues under the skin of the penis. The Company is currently conducting a Phase III clinical trial for vocal fold scarring, which is a fibrotic disorder, and has now decided to conduct a pharmacology study in an animal model of Peyronie's disease, aiming to expand the indications of HGF to include other fibrotic disorders. There is a need for drugs that directly treat fibrotic tissue in Peyronie's disease, and HGF, with its anti-fibrotic effects, could be a new therapeutic option.

In August 2025, the Company signed a collaborative research agreement with Keio University in association with the development of a new regenerative treatment of peripheral neuropathy with the use of HGF. HGF is reported to have multiple functions of accelerating the regeneration of peripheral nerves. It is also suggested that HGF has the therapeutic effects of easing neuropathic pain in the mice model. With a view to overcoming problems with surgery in peripheral nerve regeneration, the two parties will verify efficacy in using HGF and study methods of administration suited for practical application, aiming to achieve early practical application of a new therapeutic strategy.

### 2. Business development activities

During the fiscal year under review, the Company had business development discussion with potential business partners to expand development of acute SCI outside Japan. In June 2024, the Company gave an oral presentation at the 2nd Annual Spinal Cord Injury Investor Symposium in the U.S. and networked with the symposium participants. In addition, the Company issued share acquisition rights in September 2023, for the purpose of partially funding clinical development and manufacturing development (improvement of the efficiency of the manufacturing method for recombinant human HGF) for acute SCI in the U.S. The exercise of all share acquisition rights was completed in May 2024. With this move it expected to clarify the Company's development strategy in the U.S., the largest pharmaceutical market in the world, and accelerate business development activities.

In September 2021, oremepermin alfa was registered as the International Nonproprietary Name (INN) for recombinant human HGF protein (five amino acid-deleted, glycosylated; development code, KP-100), the drug substance of our development pipeline. Additionally, in May 2024, oremepermin alfa was registered as the Japanese Accepted Names for Pharmaceuticals (JAN), and this name can now be used officially in Japan in applications for manufacturing and marketing approval.

As a result of these efforts, business results for the fiscal year under review were as follows.

Net sales for the fiscal year under review amounted to \(\frac{\pmathbf{x}}{72,215}\) thousand (a year-on-year decrease of 9.8%), while the Company recorded an operating loss of \(\frac{\pmathbf{y}}{909,452}\) thousand (operating loss for the previous fiscal year was \(\frac{\pmathbf{x}}{817,882}\) thousand), ordinary loss of \(\frac{\pmathbf{y}}{914,755}\) thousand (ordinary loss for the previous fiscal year was \(\frac{\pmathbf{x}}{754,961}\) thousand) and loss of \(\frac{\pmathbf{y}}{916,255}\) thousand (loss for the previous fiscal year was \(\frac{\pmathbf{x}}{756,453}\) thousand).

Since the Company operates in a single segment of pharmaceutical development business, segment information is omitted.

## (2) Explanation of Financial Position

#### Assets

Current assets as of September 30, 2025 decreased by \(\frac{\pmathrm{\text{Y}}}{700,496}\) thousand from the end of the previous fiscal year to \(\frac{\pmathrm{\text{\text{2}}}}{255,494}\) thousand (a decrease of 25.4% from the end of the previous fiscal year). This was mainly due to a decrease of \(\frac{\pmathrm{\text{4}}}{694,387}\) thousand in cash and deposits chiefly as a result of the payment of R&D expenses. Non-current assets increased \(\frac{\pmathrm{\text{2}}}{22,746}\) thousand, rising from \(\frac{\pmathrm{1}}{1,122}\) thousand at the end of the previous fiscal year to \(\frac{\pmathrm{2}}{23,869}\) thousand. This reflected an increase of \(\frac{\pmathrm{2}}{22,746}\) thousand in guarantee deposits, chiefly due to a rise in leasehold deposits attributable to the opening of the Nakanoshima Qross Office.

As a result, total assets decreased by \$677,750 thousand from the end of the previous fiscal year to \$2,079,363 thousand (a decrease of 24.6% from the end of the previous fiscal year).

#### Liabilities

Current liabilities as of September 30, 2025 decreased by ¥18,825 thousand from the end of the previous fiscal year to ¥109,347 thousand (a decrease of 14.7% from the end of the previous fiscal year). This was mainly due to a decrease of ¥16,127 thousand in accounts payable - other. Non-current liabilities increased by ¥140,011 thousand from the end of the previous fiscal year to ¥660,760 thousand (an increase of 26.9% from the end of the previous fiscal year). This chiefly reflects an increase of ¥8,880 thousand in long-term accounts payable - other and an increase of ¥131,260 thousand in long-term deposits received.

As a result, total liabilities increased by \$121,186 thousand from the end of the previous fiscal year to \$770,107 thousand (an increase of 18.7% from the end of the previous fiscal year).

#### Net assets

Net assets as of September 30, 2025 decreased by ¥798,936 thousand from the end of the previous fiscal year to ¥1,309,255 thousand (a decrease of 37.9% from the end of the previous fiscal year). This primarily reflected the recording of a net loss of ¥916,255 thousand, which was partially offset by increases of both share capital and legal capital surplus of ¥52,876 thousand each as a result of a capital increase by way of execution of share acquisition rights. This resulted in share capital of ¥64,176 thousand, capital surplus of ¥2,888,081 thousand, and negative retained earnings of ¥1,672,709 thousand.

## (3) Explanation of Cash Flows

The balance of cash and cash equivalents ("cash") at the end of the fiscal year under review decreased \\$825,647 thousand from the end of the previous fiscal year to \\$991,296 thousand.

The status of cash flows in the fiscal year under review was as follows.

## (Cash flows from operating activities)

Net cash used in operating activities was \(\frac{\pmathbf{4755}}{782}\) thousand (net cash used in operating activities during the previous fiscal year was \(\frac{\pmathbf{4661}}{661}, 166\) thousand). This was due mainly to a loss before income taxes of \(\frac{\pmathbf{4914}}{914}, 755\) thousand and an increase in advance payments to suppliers of \(\frac{\pmathbf{434}}{344}, 485\) thousand, offsetting an increase in cash resulting from a decrease in inventories of \(\frac{\pmathbf{444}}{442}, 172\) thousand arising from a decrease in inventories.

## (Cash flows from investing activities)

Net cash used in investing activities was \$154,006 thousand (net cash used in investing activities during the previous fiscal year was \$121,363 thousand). This was mainly due to payments into time deposits of \$131,260 thousand.

# (Cash flows from financing activities)

Net cash provided by financing activities amounted to \(\frac{\text{\$\text{\}}}{84,141}\) thousand (compared with net cash provided of \(\frac{\text{\$\text{\$\text{\}}}{838,233}\) thousand in the previous fiscal year). This was chiefly owing to proceeds from issuance of shares resulting from exercise of share acquisition rights of \(\frac{\text{\$\tex{

## (4) Outlook

In net sales for the fiscal year ended September 30, 2025, the Company recorded \(\frac{\pmathbf{x}}{2}\) million, only a fixed technology access fee, which the Company receives annually starting from the first dose in the first clinical trial conducted by Claris Biotherapeutics in the U.S. In the fiscal year ending September 30, 2026, the Company expects to receive only the technology access fee from Claris as in the fiscal year under review. Net sales are expected to amount to \(\frac{\pmathbf{x}}{7}\)2 million (a decrease of 0.3% year on year).

In terms of selling, general and administrative expenses, the Company anticipates personnel expenses accompanied by a strengthening the structures of the Research and Development Department and the Administrative Department, various relevant expenses in response to the staff increase, expenses for conducting an additional clinical trial for the acute SCI pipeline, expenses for clinical trial activities and prototyping a formulation for the VFS pipeline, expenses for new collaborative research with a university, and expenses for a toxicity test associated with the development of acute SCI treatment in the United States, among others. Consequently, the Company forecasts selling, general and administrative expenses of ¥1,244 million for the fiscal year ending September 30, 2026 compared with ¥981 million for the fiscal year ended September 30, 2025 (an increase of 26.7% year on year).

As a result, operating loss for the fiscal year ending September 30, 2026 is projected to be \(\frac{\pmathbf{4}}{1}\),172 million (compared to an operating loss of \(\frac{\pmathbf{4}}{909}\) million in the fiscal year under review).

The Company expects no non-operating income or expense at the time of creating the forecast. The ordinary loss for the fiscal year ending September 30, 2026 will be \(\frac{\pmathbf{1}}{1,172}\) million (compared to an ordinary loss of \(\frac{\pmathbf{9}}{9}14\) million in the fiscal year under review). There are no extraordinary income or losses projected as of the date of preparation of the forecast, and the loss for the fiscal year ending September 30, 2026 is expected to total \(\frac{\pmathbf{1}}{1,173}\) million (compared to a loss of \(\frac{\pmathbf{9}}{9}16\) million in the fiscal year under review).

## (5) Important Matters Related to Going Concern Assumption

The Company falls under the category of biotech companies. One of their characteristics is that a large amount of research and development expenses and a long period of time are required before the commercialization of a drug and the earning of revenue. The Company is striving to develop multiple pipelines in a bid to commercialize HGF drugs, but it has yet to earn any revenue.

With regard to the acute SCI pipeline, which is a principal pipeline, Phase I/II clinical trials and Phase III clinical trials finished, and the Company consulted with the PMDA with a view to filing an application for approval. In July 2025, it decided to file the application for approval after conducting an additional clinical trial.

Consequently, the Company's financing capacity declined, partly due to the continued occurrence of operating losses, the posting of negative cash flows from operating activities and delays in the timing of the application for approval from the initial schedule. Under these circumstances, the Company judges that the current situation leads to significant doubt about its going concern assumption.

To resolve this situation, the Board of Directors adopted a resolution at a meeting held on July 16, 2025 to issue the 16th series of share acquisition rights through a third-party allotment. Consequently, the third-party allotment took place on August 1, 2025. The Company judges that there is currently no material uncertainty on the going concern assumption, given that it is possible for it to secure funds for continuing its business operations with funds raised through the exercise of the aforementioned share acquisition rights and by reconsidering its own pipelines to cut research and development expenses and reduce general expenses as needed.

In addition, the Company will continue to conduct the drug development activities and business development activities stated below, as well as other efforts to strengthen its business and financial foundations and to remove and remediate the situation.

### (i) Securing of sources of continuous revenue

In addition to sales revenue from Claris Biotherapeutics, Inc. in the form of sales from the supply of drug substances and technology access fees, the Company is carrying out collaborative research and development concerning HGF drugs in an effort to earn revenue from the sale of resulting drug substances.

## (ii) Cultivation of collaboration partners for the existing pipelines

In association with the Company's acute SCI pipeline in Japan, it has already signed agreements on exclusive sales and wholesale rights with a pharmaceutical firm. For the VFS pipeline, ALS pipeline and the overseas acute SCI pipeline, no partnerships with any pharmaceutical or other company has been confirmed to date.

With respect to the domestic VFS pipeline, the Company seeks commercialization in the model of acquiring approval of pharmaceuticals through independent development and securing sales partners, as in the domestic acute SCI pipeline. For the overseas acute SCI and VFS pipelines and the global ALS pipeline, the Company seeks commercialization in the model of out-licensing and collaborative development. For the individual pipelines, the Company is working to reduce development and financial risks through swift negotiations for partnerships with pharmaceutical and other companies.

#### (iii) Financing

The Company is endeavoring to procure funds with the utilization of subsidies and other sources.

## 2. Basic Policy in Selection of Accounting Standard

As the Company does not prepare consolidated financial statements, financial statements are prepared in accordance with Japanese GAAP, considering the burden of preparing systems to enable the preparation of financial statements in accordance with International Financial Reporting Standards, among other matters.

# 3. Financial Statements and Principal Notes

# (1) Balance Sheets

		(Thousand ye
	As of September 30, 2024	As of September 30, 2025
Assets		
Current assets		
Cash and deposits	2,313,475	1,619,088
Raw materials and supplies	294,514	250,342
Advance payments to suppliers	66,757	101,243
Prepaid expenses	23,966	20,156
Consumption taxes receivable	57,249	60,707
Other	27	3,956
Total current assets	2,755,990	2,055,494
Non-current assets		
Property, plant and equipment	-	_
Investments and other assets		
Guarantee deposits	1,122	23,869
Total investments and other assets	1,122	23,869
Total non-current assets	1,122	23,869
Total assets	2,757,113	2,079,363
Liabilities		
Current liabilities		
Accounts payable - other	36,442	20,315
Accrued expenses	21,494	15,594
Income taxes payable	1,490	1,490
Advances received	64,751	66,206
Deposits received	3,994	5,740
Total current liabilities	128,172	109,347
Non-current liabilities		
Asset retirement obligations	2,305	2,176
Long-term accounts payable - other	21,911	30,792
Long-term deposits received	496,531	627,792
Total non-current liabilities	520,748	660,760
Total liabilities	648,921	770,107
Net assets		,
Shareholders' equity		
Share capital	11,300	64,176
Capital surplus	,	- 1,2 / 0
Legal capital surplus	2,271,162	2,324,039
Other capital surplus	564,042	564,042
Total capital surplus	2,835,204	2,888,081
Retained earnings	2,050,201	2,000,001
Other retained earnings		
Retained earnings brought forward	(756,453)	(1,672,709)
Total retained earnings	(756,453)	(1,672,709)
Treasury shares	(106)	(1,072,709)
Total shareholders' equity	2,089,944	1,279,402
Share acquisition rights	18,247	29,853
Total net assets	2,108,192	1,309,255
Total liabilities and net assets	2,757,113	2,079,363

# (2) Statements of Income

Ordinary loss

Loss

Loss before income taxes

Income taxes - current

Total income taxes

(Thousand yen) For the fiscal year ended For the fiscal year ended September 30, 2024 September 30, 2025 Net sales 80,038 72,215 Cost of sales Beginning finished goods inventory Cost of products manufactured Total Ending finished goods inventory Cost of finished goods sold Gross profit 80,038 72,215 Selling, general and administrative expenses 897,920 981,667 Operating loss (817,882) (909,452)Non-operating income Interest income 10 67 62,011 Subsidy income Reagent sales income 1,400 717 Foreign exchange gains Interest on tax refund 179 112 Other 4 Total non-operating income 62,920 1,585 Non-operating expenses 6,645 Share acquisition rights issuance costs Foreign exchange losses 243 6,888 Total non-operating expenses (914,755)

(754,961)

(754,961)

1,491

1,491 (756,453) (914,755)

(916,255)

1,500

1,500

# (3) Statements of Changes in Net Assets

For the fiscal year ended September 30, 2024 (From October 1, 2023 to September 30, 2024)

(Thousand yen)

	Shareholders' equity					
		Capital surplus				
	Share capital	Legal capital surplus	Other capital surplus	Total capital surplus		
Balance at beginning of period	97,546	2,531,474	564,042	3,095,517		
Changes during period						
Issuance of new shares (Exercise of share acquisition rights)	419,711	419,711		419,711		
Restricted stock compensation						
Capital reduction	(505,957)	(680,023)	1,185,981	505,957		
Deficit disposition			(1,185,981)	(1,185,981)		
Loss						
Purchase of treasury shares						
Net changes in items other than shareholders' equity						
Total changes during period	(86,246)	(260,312)	_	(260,312)		
Balance at end of period	11,300	2,271,162	564,042	2,835,204		

		Sharehold	ers' equity			
	Retained	earnings				
	Other retained earnings	Total retained	Treasury shares	Total shareholders' equity	Share acquisition rights	Total net assets
	Retained earnings brought forward	earnings		equity		
Balance at beginning of period	(1,185,981)	(1,185,981)	(75)	2,007,006	14,696	2,021,702
Changes during period						
Issuance of new shares (Exercise of share acquisition rights)				839,422		839,422
Restricted stock compensation				_		_
Capital reduction				-		-
Deficit disposition	1,185,981	1,185,981		_		_
Loss	(756,453)	(756,453)		(756,453)		(756,453)
Purchase of treasury shares			(31)	(31)		(31)
Net changes in items other than shareholders' equity					3,551	3,551
Total changes during period	429,528	429,528	(31)	82,938	3,551	86,489
Balance at end of period	(756,453)	(756,453)	(106)	2,089,944	18,247	2,108,192

# For the fiscal year ended September 30, 2025 (From October 1, 2024 to September 30, 2025)

(Thousand yen)

	Shareholders' equity						
		Capital surplus					
	Share capital	Legal capital surplus	Other capital surplus	Total capital surplus			
Balance at beginning of period	11,300	2,271,162	564,042	2,835,204			
Changes during period							
Issuance of new shares (Exercise of share acquisition rights)	45,264	45,264		45,264			
Restricted stock compensation	7,612	7,612		7,612			
Capital reduction							
Deficit disposition							
Loss							
Purchase of treasury shares							
Net changes in items other than shareholders' equity							
Total changes during period	52,876	52,876	_	52,876			
Balance at end of period	64,176	2,324,039	564,042	2,888,081			

		Sharehold	ers' equity			
	Retained	earnings				
	Other retained earnings	Total retained	Treasury shares	Total shareholders' equity	Share acquisition rights	Total net assets
	Retained earnings brought forward	earnings		- 4		
Balance at beginning of period	(756,453)	(756,453)	(106)	2,089,944	18,247	2,108,192
Changes during period						
Issuance of new shares (Exercise of share acquisition rights)				90,528		90,528
Restricted stock compensation				15,225		15,225
Capital reduction				-		-
Deficit disposition				-		-
Loss	(916,255)	(916,255)		(916,255)		(916,255)
Purchase of treasury shares			(40)	(40)		(40)
Net changes in items other than shareholders' equity					11,606	11,606
Total changes during period	(916,255)	(916,255)	(40)	(810,542)	11,606	(798,936)
Balance at end of period	(1,672,709)	(1,672,709)	(147)	1,279,402	29,853	1,309,255

# (4) Statements of Cash Flows

	For the fiscal year ended September 30, 2024	(Thousand yen  For the fiscal year ended September 30, 2025
Cash flows from operating activities		
Loss before income taxes	(754,961)	(914,755)
Interest and dividend income	(10)	(67)
Share acquisition rights issuance costs	-	6,645
Subsidy income	(62,011)	_
Decrease (increase) in trade receivables	7,560	-
Decrease (increase) in inventories	69,541	44,172
Decrease (increase) in accounts receivable - other	17,041	(7,388)
Decrease (increase) in advance payments to suppliers	(45,691)	(34,485)
Decrease (increase) in prepaid expenses	(9,964)	3,810
Increase (decrease) in accounts payable - other	(135,219)	(16,127)
Increase (decrease) in advances received	64,751	1,455
Increase (decrease) in long-term accounts payable - other	11,566	8,880
Other	20,420	22,251
Subtotal —	(816,977)	(885,609)
Interest and dividends received	10	67
Subsidies received	36,011	_
Proceeds from long-term deposits received	121,281	131,260
Income taxes paid	(1,491)	(1,500)
Net cash provided by (used in) operating activities	(661,166)	(755,782)
Cash flows from investing activities		
Payments of leasehold and guarantee deposits	(82)	(23,869)
Proceeds from refund of leasehold and guarantee deposits	-	1,122
Payments into time deposits	(121,281)	(131,260)
Net cash provided by (used in) investing activities	(121,363)	(154,006)
Cash flows from financing activities		
Purchase of treasury shares	(31)	(40)
Proceeds from issuance of share acquisition rights	-	1,003
Proceeds from issuance of shares resulting from exercise of share acquisition rights	838,265	83,179
Net cash provided by (used in) financing activities	838,233	84,141
Net increase (decrease) in cash and cash equivalents	55,703	(825,647)
Cash and cash equivalents at beginning of period	1,761,239	1,816,943
Cash and cash equivalents at end of period	1,816,943	991,296

# (5) Notes to Financial Statements

# Notes on going concern assumption

Not applicable.

# Equity method earnings, etc.

Not applicable.

# Revenue recognition

Information on disaggregated revenue from contracts with customers

The Company operates in a single segment of pharmaceutical development business. Revenue disaggregated by main goods and services are as follows.

(Thousand yen)

Item	Fiscal year ended September 30, 2024	Fiscal year ended September 30, 2025
Lump-sum revenue from contracts	_	ı
Milestone revenue	_	_
Royalty income	73,841	72,215
Revenue from product sales	6,197	_
Revenue from contracts with customers	80,038	72,215
Other revenue	-	-
Revenues from external customers	80,038	72,215

# **Segment information**

Since the Company operates in a single segment of pharmaceutical development business, segment information is omitted.

### Per share information

	Previous fiscal year (October 1, 2023 to September 30, 2024)	Fiscal year under review (October 1, 2024 to September 30, 2025)
Net assets per share	¥306.87	¥182.30
Net loss per share	(¥118.21)	(¥133.92)

Notes: 1. Although potential shares existed, diluted earnings per share are not shown, as a net loss per share was recorded.

2. The basis for the calculation of net loss per share is as follows.

Item	Previous fiscal year (October 1, 2023 to September 30, 2024)	Fiscal year under review (October 1, 2024 to September 30, 2025)
Net loss per share		
Loss (thousand yen)	(756,453)	(916,255)
Amount not attributable to common shareholders (thousand yen)	-	1
Loss on common shares (thousand yen)	(756,453)	(916,255)
Average number of common shares during the period (shares)	6,399,270	6,841,997
Overview of potential shares not included in the calculation of diluted earnings per share due to lack of dilutive effect	_	

3. The basis for the calculation of net assets per share is as follows.

Item	Previous fiscal year (As of September 30, 2024)	Fiscal year under review (As of September 30, 2025)
Total net assets (thousand yen)	2,108,192	1,309,255
Amount deducted from total net assets (thousand yen)	18,247	29,853
(Of which share acquisition rights (thousand yen))	[18,247]	[29,853]
Net assets related to common shares at the end of the period (thousand yen)	2,089,944	1,279,402
Number of common shares at the end of the period used for the calculation of net assets per share (shares)	6,810,564	7,018,017

# Significant subsequent events

(Establishment of a subsidiary)

The Company resolved, at a meeting of its Board of Directors held on October 15, 2025, to establish a subsidiary as detailed below. The subsidiary was established on November 3, 2025.

# 1. Purpose of establishing the subsidiary

The subsidiary was established for the purpose of accelerating and stepping up development for spinal cord injuries (SCI) in the United States.

# 2. Profile of the subsidiary

•	
(1) Name	Kringle Pharma USA, Inc.
(2) Location	Georgia, USA
(3) Title and name of representative	Matt Vogelhuber, President
(4) Business	Research and development of pharmaceuticals and incidental businesses
(5) Fiscal year-end	September
(6) Share capital	10,000 dollars
(7) Established	November 3, 2025
(8) Major shareholders and their shareholding ratios	Kringle Pharma, Inc. 100%

# (Exercise of share acquisition rights)

During the period between October 1, 2025 and November 12, 2025, the 16th series of share acquisition rights were exercised. An overview of the exercise of these share acquisition rights is shown below.

1. Number of share acquisition rights exercised: 1,670

2. Type and number of shares issued: 167,000 common shares

3. Increase in share capital: ¥37,381 thousand

4. Increase in legal capital surplus: ¥37,381 thousand