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Financial Results for the Three Months Ended December 31, 2024 [Japanese GAAP] (Non-consolidated)

February 7, 2025

Company name: Kringle Pharma, Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4884
URL: https://www.kringle-pharma.com/en/
Representative: Kiichi Adachi, President & CEO
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Scheduled date of commencing dividend payments: —
Availability of supplementary explanatory materials on financial results: Available
Schedule of financial results briefing session: Scheduled

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

1. Financial Results for the Three Months Ended December 31, 2024 (October 1, 2024 - December 31, 2024)

(1) Operating Results

(% indicates changes from the previous corresponding period.)

	Net sales		Operating profit		Ordinary profit		Profit	
Three months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
December 31, 2024	18	(2.8)	(212)	–	(212)	–	(212)	–
December 31, 2023	18	7.6	(168)	–	(169)	–	(169)	–

	Basic earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
December 31, 2024	(31.23)	–
December 31, 2023	(29.53)	–

(2) Financial Position

	Total assets	Net assets	Equity ratio
As of	Million yen	Million yen	%
December 31, 2024	2,544	1,899	73.8
September 30, 2024	2,757	2,108	75.8

Reference: Equity: As of December 31, 2024: ¥1,877 million As of September 30, 2024: ¥2,089 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended September 30, 2024	–	0.00	–	0.00	0.00
Fiscal year ending September 30, 2025	–				
Fiscal year ending September 30, 2025 (Forecast)		0.00	–	0.00	0.00

Note: Revision to the dividend forecast announced most recently: None

3. Financial Results Forecast for the Fiscal Year Ending September 30, 2025 (October 1, 2024 - September 30, 2025)

(% indicates changes from the previous corresponding period.)

	Net sales		Operating profit		Ordinary profit		Profit		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
Full year	272	239.8	(1,379)	–	(1,379)	–	(1,380)	–	(202.70)

Note: Revision to the financial results forecast announced most recently: None

*** Notes:**

(1) Accounting methods adopted particularly for the preparation of quarterly financial statements: None

(2) 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

(3) 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 December 31, 2024:	6,810,700 shares
As of September 30, 2024:	6,810,700 shares

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

As of December 31, 2024:	136 shares
As of September 30, 2024:	136 shares

3) Average number of shares during the period:

For the three months ended December 31, 2024:	6,810,564 shares
For the three months ended December 31, 2023:	5,739,389 shares

* Review of the accompanying quarterly financial statements by certified public accountants or audit corporations: None

* 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. Actual results may differ significantly from these forecasts due to various factors.

Table of Contents - Attachments

1. Overview of Financial Results

(1) Overview of Quarterly Business Performance

The forward-looking statements herein are based on the judgments of Kringle Pharma, Inc. (the "Company") as of the end of the first quarter 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, held 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, and is now preparing to file an application.

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[*1].

*1 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 Osaka Prefectural Government for Type 1 Pharmaceuticals Manufacturing and Sales Business licenses needed for making applications for manufacturing and marketing approval. *2

*2 The Company obtained Type 1 Pharmaceuticals Manufacturing and Sales Business licenses from Osaka Prefectural Government as of January 7, 2025.

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 June 2021, the APSS Congress Best Clinical Research Award was given for the presentation on Phase I/II clinical trial for acute SCI at the 13th Combined Meeting of Asia Pacific Spine Society & Asia Pacific Paediatric Orthopaedic Society (APSS-APPOS 2021; held from June 9 to 12, 2021 at Kobe International Conference Center).

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)

For VFS, a disorder in which the vocal fold mucosa hardens and degenerates (fibrosis), an investigator-initiated Phase I/II clinical trial confirmed the safety of intracordal administration of the recombinant human HGF. It also detected signals of efficacy showing functional recovery of the vocal cord with some patients (J Tissue Eng Regen Med. 2017; 1-8.).

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. Sanno Medical Center was newly added in May 2024, and case registration is currently moving forward at a total of six 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).

(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 first three months of 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 addition, the Company has been conducting collaborative research with Tokyo Medical and Dental University (now Institute of Science Tokyo) since October 2018. In July 2022, the university performed the first autologous intestinal organoid transplantation treatment aimed at repairing intractable ulcers in ulcerative colitis. KP-100 developed by the Company was used to produce the intestinal organoid used in this transplantation treatment.

In September 2022, the Company decided to promote open innovation to pursue further potential of HGF proteins by seeking new research proposals from researchers regarding the use of HGF proteins.

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.

2. Business development activities

During the three months ended December 31, 2024, 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, during the three months ended December 31, 2024, net sales amounted to ¥18,161 thousand (a year-on-year decrease of 2.8%), while the Company recorded an operating loss of ¥212,191 thousand (operating loss during the three months ended December 31, 2023 was ¥168,592 thousand), ordinary loss of ¥212,309 thousand (ordinary loss during the three months ended December 31, 2023 was ¥169,113 thousand) and loss of ¥212,682 thousand (loss during the three months ended December 31, 2023 was ¥169,486 thousand).

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

(2) Overview of Quarterly Financial Condition

Assets

Current assets as of December 31, 2024 decreased by ¥212,199 thousand from the end of the previous fiscal year to ¥2,543,791 thousand (a decrease of 7.7% from the end of the previous fiscal year). This was mainly due to a decrease of ¥211,929 thousand in cash and deposits as a result of the payment of R&D expenses including VFS clinical trial expenses. Non-current assets amounted to ¥1,122 thousand, equaling the amount at the end of the previous fiscal year in the absence of any fluctuation in non-current assets from the end of the previous fiscal year.

As a result, total assets decreased by ¥212,199 thousand from the end of the previous fiscal year to ¥2,544,914 thousand (a decrease of 7.7% from the end of the previous fiscal year).

Liabilities

Current liabilities as of December 31, 2024 decreased by ¥4,692 thousand from the end of the previous fiscal year to ¥123,480 thousand (a decrease of 3.7% from the end of the previous fiscal year). The main factor behind this was a

decrease in advances received of ¥18,161 thousand, which offset increases in accounts payable – other of ¥10,795 thousand and asset retirement obligation planned to be performed within a year of ¥2,305 thousand. Non-current liabilities increased by ¥1,382 thousand from the end of the previous fiscal year to ¥522,130 thousand (an increase of 0.3% from the end of the previous fiscal year). This reflected an increase in long-term accounts payable - other of ¥3,687 thousand, which offset a decrease in asset retirement obligations as a result of reclassification to current assets.
As a result, total liabilities decreased by ¥3,309 thousand from the end of the previous fiscal year to ¥645,611 thousand (a decrease of 0.5% from the end of the previous fiscal year).

Net assets
Net assets as of December 31, 2024 decreased by ¥208,889 thousand from the end of the previous fiscal year to ¥1,899,302 thousand (a decrease of 9.9% from the end of the previous fiscal year). This was primarily due to the recording of a loss of ¥212,682 thousand.
This resulted in share capital of ¥11,300 thousand, capital surplus of ¥2,835,204 thousand, and negative retained earnings of ¥969,135 thousand.

(3) Explanation of Financial Results Forecast and Other Forward-looking Information

The financial results forecast for the fiscal year ending September 30, 2025 (October 1, 2024 - September 30, 2025) is unchanged from the forecast announced in “Financial Results for the Fiscal Year Ended September 30, 2024” on November 13, 2024.

2. Quarterly Financial Statements and Principal Notes

(1) Quarterly Balance Sheets

(Thousand yen)

	As of September 30, 2024	As of December 31, 2024
Assets		
Current assets		
Cash and deposits	2,313,475	2,101,546
Raw materials and supplies	294,514	283,203
Advance payments to suppliers	66,757	67,952
Consumption taxes receivable	57,249	71,647
Other	23,993	19,441
Total current assets	2,755,990	2,543,791
Non-current assets		
Property, plant and equipment	–	–
Investments and other assets	1,122	1,122
Total non-current assets	1,122	1,122
Total assets	2,757,113	2,544,914
Liabilities		
Current liabilities		
Accounts payable - other	36,442	47,238
Income taxes payable	1,490	372
Asset retirement obligations	–	2,305
Advances received	64,751	46,589
Other	25,488	26,974
Total current liabilities	128,172	123,480
Non-current liabilities		
Asset retirement obligations	2,305	–
Long-term accounts payable - other	21,911	25,598
Long-term deposits received	496,531	496,531
Total non-current liabilities	520,748	522,130
Total liabilities	648,921	645,611
Net assets		
Shareholders' equity		
Share capital	11,300	11,300
Capital surplus	2,835,204	2,835,204
Retained earnings	(756,453)	(969,135)
Treasury shares	(106)	(106)
Total shareholders' equity	2,089,944	1,877,262
Share acquisition rights	18,247	22,040
Total net assets	2,108,192	1,899,302
Total liabilities and net assets	2,757,113	2,544,914

(2) Quarterly Statements of Income

Three Months Ended December 31

(Thousand yen)

	For the three months ended December 31, 2023	For the three months ended December 31, 2024
Net sales	18,690	18,161
Cost of sales	–	–
Gross profit	18,690	18,161
Selling, general and administrative expenses	187,283	230,353
Operating loss	(168,592)	(212,191)
Non-operating income		
Subsidy income	544	–
Total non-operating income	544	–
Non-operating expenses		
Foreign exchange losses	1,064	117
Total non-operating expenses	1,064	117
Ordinary loss	(169,113)	(212,309)
Loss before income taxes	(169,113)	(212,309)
Income taxes - current	372	372
Total income taxes	372	372
Loss	(169,486)	(212,682)

(3) Notes to Quarterly Financial Statements

Notes on going concern assumption

Not applicable.

Notes on quarterly balance sheet

Collateral assets and loans pledged as collateral

Fixed deposits included in cash and deposits are collateral assets for long-term deposits received from Japan Agency for Medical Research and Development (AMED).

Collateral assets

	As of September 30, 2024	As of December 31, 2024
Cash and deposits	¥496,531 thousand	¥496,531 thousand

Loans pledged as collateral

	As of September 30, 2024	As of December 31, 2024
Long-term deposits received	¥496,531 thousand	¥496,531 thousand

Notes on quarterly statement of cash flows

For the three months ended December 31, 2023

The Group has not prepared a quarterly statement of cash flows for the first three months of the fiscal year under review. There is no depreciation (including amortization of intangible assets) for the first three months of the fiscal year under review.

For the three months ended December 31, 2024

The Group has not prepared a quarterly statement of cash flows for the first three months of the fiscal year under review. There is no depreciation (including amortization of intangible assets) for the first three months of the fiscal year under review.

Notes in case of significant changes in shareholders' equity

For the three months ended December 31, 2023

On September 4, 2023, the Company allotted its 13th series of share acquisition rights to Barclays Bank PLC. Chiefly due to the exercise of the 13th series of share acquisition rights during the first three months of the fiscal year under review, share capital and capital surplus increased by ¥257,048 thousand each.

As a result, as of December 31, 2023, share capital and capital surplus amounted to ¥354,595 thousand and ¥3,352,566 thousand, respectively.

For the three months ended December 31, 2024

Not applicable.

Notes on segment information, etc.

Segment information

For the three months ended December 31, 2023

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

For the three months ended December 31, 2024

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