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Financial Results for the Three Months Ended December 31, 2023 [Japanese GAAP] (Non-consolidated)

February 9, 2024

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 filing quarterly securities report: February 9, 2024
Scheduled date of commencing dividend payments: —
Availability of supplementary explanatory materials on quarterly financial results: Available
Schedule of quarterly 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, 2023 (October 1, 2023 - December 31, 2023)

(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, 2023	18	7.6	(168)	–	(169)	–	(169)	–
December 31, 2022	17	25.8	(157)	–	(157)	–	(157)	–

	Basic earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
December 31, 2023	(29.53)	–
December 31, 2022	(29.34)	–

(2) Financial Position

	Total assets	Net assets	Equity ratio
As of	Million yen	Million yen	%
December 31, 2023	2,844	2,361	82.7
September 30, 2023	2,618	2,021	76.6

Reference: Equity: As of December 31, 2023: ¥2,351 million As of September 30, 2023: ¥2,007 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, 2023	–	0.00	–	0.00	0.00
Fiscal year ending September 30, 2024	–				
Fiscal year ending September 30, 2024 (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, 2024 (October 1, 2023 - September 30, 2024)

(% 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	292.8	(1,133)	–	(1,107)	–	(1,109)	–	(180.12)

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, 2023:	6,298,500 shares
As of September 30, 2023:	5,522,200 shares

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

As of December 31, 2023:	87 shares
As of September 30, 2023:	87 shares

3) Average number of shares during the period:

For the three months ended December 31, 2023:	5,739,389 shares
For the three months ended December 31, 2022:	5,380,613 shares

* These quarterly financial results are outside the scope of quarterly review by certified public accountants or an audit firm.

* 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.

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1. Qualitative Information on Quarterly 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 first quarter under review.

In the Japanese pharmaceutical market during the three months ended December 31, 2023, 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.

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.

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 two fiscal years ago. Process validation for manufacturing of the drug product was also completed in the previous fiscal year.

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 newly added as medical institutions for carrying out clinical trials, and case registration is currently moving forward at a total of five 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. Going forward, the Company plans to undertake additional analysis including biomarker evaluation in cooperation with Tohoku University, for which approval of the Institutional Review Board (IRB) of Tohoku University Graduate School of Medicine has already been obtained.

(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.

During the 21st term, the Company supplied Claris with HGF drug substance required for manufacturing of investigational drugs but there was no supply of HGF drug substance during the first three months under review. 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. As now the trial continues in both the U.S. and Canada, further acceleration of patient enrolment is expected.

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.

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

(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 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 by seeking new research proposals from researchers regarding the use of recombinant human HGF.

Moreover, in September 2023, the Company issued share acquisition rights, and decided to use part of the funds raised for the creation of a new pipeline including the implementation and expansion of joint non-clinical research.

2. Business development activities

During the three months ended December 31, 2023, the Company had business development discussion with potential business partners to expand development of acute SCI outside Japan. 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. 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 alliance discussions.

In September 2021, "oremepermin alfa" was registered as the International Nonproprietary Name (INN) for recombinant human HGF (five amino acid-deleted, glycosylated; development code, KP-100), the drug substance of our development pipeline.

As a result of these efforts, during the three months ended December 31, 2023, net sales amounted to ¥18,690 thousand (a year-on-year increase of 7.6%), while the Company recorded an operating loss of ¥168,592 thousand (operating loss during the three months ended December 31, 2022 was ¥157,467 thousand), ordinary loss of ¥169,113 thousand (ordinary loss during the three months ended December 31, 2022 was ¥157,476 thousand) and loss of ¥169,486 thousand (loss during the three months ended December 31, 2022 was ¥157,849 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 December 31, 2023 increased by ¥225,959 thousand from the end of the previous fiscal year to ¥2,843,577 thousand (an increase of 8.6% from the end of the previous fiscal year). This primarily reflected increases in cash and deposits of ¥204,904 thousand and accounts receivable - trade of ¥17,433 thousand, mainly as a result of capital increase by way of execution of share acquisition rights. Non-current assets increased by ¥82 thousand from the end of the previous fiscal year to ¥1,122 thousand (an increase of 7.9% from the end of the previous fiscal year). This resulted from an increase in investments and other assets of ¥82 thousand.

As a result, total assets increased by ¥226,041 thousand from the end of the previous fiscal year to ¥2,844,699 thousand (an increase of 8.6% from the end of the previous fiscal year).

Liabilities

Current liabilities as of December 31, 2023 decreased by ¥115,304 thousand from the end of the previous fiscal year to ¥93,750 thousand (a decrease of 55.2% from the end of the previous fiscal year). This was mainly due to a decrease of ¥117,408 thousand in accounts payable - other. Non-current liabilities increased by ¥1,565 thousand from the end of the previous fiscal year to ¥389,466 thousand (an increase of 0.4% from the end of the previous fiscal year). This was due to an increase in long-term accounts payable - other of ¥1,565 thousand.

As a result, total liabilities decreased by ¥113,738 thousand from the end of the previous fiscal year to ¥483,216 thousand (a decrease of 19.1% from the end of the previous fiscal year).

Net assets

Net assets as of December 31, 2023 increased by ¥339,780 thousand from the end of the previous fiscal year to ¥2,361,483 thousand (an increase of 16.8% from the end of the previous fiscal year). This was mainly due to increases of ¥257,048 thousand in both share capital and legal capital surplus due to a capital increase as a result of the exercise of share acquisition rights, which offset the recording of a loss of ¥169,486 thousand.

This resulted in share capital of ¥354,595 thousand, capital surplus of ¥3,352,566 thousand, and negative retained earnings of ¥1,355,467 thousand.

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

The financial results forecast for the fiscal year ending September 30, 2024 (October 1, 2023 - September 30, 2024) is unchanged from the forecast announced in “Financial Results for the Fiscal Year Ended September 30, 2023” on November 13, 2023.

2. Quarterly Financial Statements and Principal Notes

(1) Quarterly Balance Sheets

(Thousand yen)

	As of September 30, 2023	As of December 31, 2023
Assets		
Current assets		
Cash and deposits	2,136,490	2,341,394
Accounts receivable - trade	7,560	24,994
Raw materials and supplies	364,056	364,056
Advance payments to suppliers	21,065	12,966
Consumption taxes receivable	74,290	87,624
Other	14,154	12,540
Total current assets	2,617,617	2,843,577
Non-current assets		
Property, plant and equipment	–	–
Investments and other assets	1,040	1,122
Total non-current assets	1,040	1,122
Total assets	2,618,657	2,844,699
Liabilities		
Current liabilities		
Accounts payable - other	171,662	54,253
Income taxes payable	1,490	372
Advances received	26,000	26,000
Other	9,901	13,123
Total current liabilities	209,054	93,750
Non-current liabilities		
Asset retirement obligations	2,305	2,305
Long-term accounts payable - other	10,345	11,910
Long-term deposits received	375,250	375,250
Total non-current liabilities	387,900	389,466
Total liabilities	596,955	483,216
Net assets		
Shareholders' equity		
Share capital	97,546	354,595
Capital surplus	3,095,517	3,352,566
Retained earnings	(1,185,981)	(1,355,467)
Treasury shares	(75)	(75)
Total shareholders' equity	2,007,006	2,351,618
Share acquisition rights	14,696	9,865
Total net assets	2,021,702	2,361,483
Total liabilities and net assets	2,618,657	2,844,699

(2) Quarterly Statements of Income

Three Months Ended December 31

(Thousand yen)

	For the three months ended December 31, 2022	For the three months ended December 31, 2023
Net sales	17,365	18,690
Cost of sales	–	–
Gross profit	17,365	18,690
Selling, general and administrative expenses	174,832	187,283
Operating loss	(157,467)	(168,592)
Non-operating income		
Subsidy income	–	544
Total non-operating income	–	544
Non-operating expenses		
Foreign exchange losses	9	1,064
Total non-operating expenses	9	1,064
Ordinary loss	(157,476)	(169,113)
Loss before income taxes	(157,476)	(169,113)
Income taxes - current	372	372
Total income taxes	372	372
Loss	(157,849)	(169,486)

(3) Notes to Quarterly Financial Statements

Notes on going concern assumption

Not applicable.

Notes in case of significant changes in shareholders' equity

For the three months ended December 31, 2022

Not applicable.

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.

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	For the three months ended December 31, 2022	For the three months ended December 31, 2023
Lump-sum revenue from contracts	–	–
Milestone revenue	–	–
Royalty income	17,365	18,690
Revenue from product sales	–	–
Revenue from contracts with customers	17,365	18,690
Other revenue	–	–
Revenues from external customers	17,365	18,690

Significant subsequent events

Exercise of share acquisition rights

During the period between January 1, 2024 and February 9, 2024, the 13th 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 2,131
2. Type and number of shares issued 213,100 common shares
3. Increase in share capital ¥77,601 thousand
4. Increase in legal capital surplus ¥77,601 thousand