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Financial Results for the Three Months Ended December 31, 2021
[Japanese GAAP]
(Non-consolidated)

February 14, 2022

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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Phone: +81-72-641-8739
Scheduled date of filing quarterly securities report: February 14, 2022
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, 2021 (October 1, 2021 - December 31, 2021)

(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, 2021	13	(85.4)	(120)	—	(128)	—	(129)	—
December 31, 2020	94	—	(45)	—	(61)	—	(62)	—

	Basic earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
December 31, 2021	(29.02)	—
December 31, 2020	(16.94)	—

Note: 1. The changes from the previous corresponding period for the three months ended December 31, 2020 are not presented as the Company did not prepare the quarterly financial statements for the three months ended December 31, 2019.
2. Although potential shares existed, diluted earnings per share are not shown, as a net loss per share was recorded.

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of December 31, 2021	2,662	2,531	95.1
As of September 30, 2021	2,635	2,506	95.1

Reference: Equity: As of December 31, 2021: ¥2,531 million
As of September 30, 2021: ¥2,506 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, 2021	—	—	—	0.00	0.00
Fiscal year ending September 30, 2022	—				

Fiscal year ending September 30, 2022 (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, 2022 (October 1, 2021 - September 30, 2022)

(% 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	355	22.6	(1,357)	—	(1,295)	—	(1,297)	—	(299.22)

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: Yes
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, 2021: 4,594,600 shares
As of September 30, 2021: 4,334,700 shares

2) Total number of treasury shares at the end of the period:
As of December 31, 2021: 40 shares
As of September 30, 2021: 40 shares

3) Average number of shares during the period:
For the three months ended December 31, 2021: 4,445,649 shares
For the three months ended December 31, 2020: 3,679,222shares

Note: We conducted a 20-for-1 share split on November 12, 2020. Total number of issued and outstanding shares, total number of treasury shares, and average number of shares are calculated as if the share split had taken place at the beginning of fiscal year ended September 30, 2021.

* 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, 2021, substitution by generic drugs progressed in response to the increase in medical costs associated with the aging of the population. Drug prices are declining significantly due to the forced NHI price revision by the government that now occurs annually from 2021. Development costs of new drugs are increasing to accommodate the growing scale of clinical trials, which is accelerating alliances and M&As between pharmaceutical companies in Japan and overseas in order to expand their corporate scale. Companies are focusing their R&D efforts on selected therapeutic areas of priority and actively looking for in-licensing opportunities outside the 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. Thus, biotech companies now assume a greater role because they usually concentrate their resources on a certain specific field and are swift and agile to make decisions. 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. In addition, the Conditional Early Approval System and the SAKIGAKE Designation System for pioneering drugs have been legislated in order to promote drug discovery in Japan.

On the other hand, although the spread of COVID-19 has increased public interest in the pharmaceutical industry, more pharmaceutical resources are currently directed to development of vaccines and treatments for COVID-19, causing potential delay in clinical development of other drugs.

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, as the Company believes development of recombinant human HGF protein 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. With the addition of Japanese Red Cross Kobe Hospital and Aijinkai Rehabilitation Hospital in March 2021, the phase III clinical trial continued to proceed during the three months ended December 31, 2021, in line with plans at the five medical facilities where patients are being enrolled.

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) is currently underway as planned for the drug substance, which is required for the submission, using the same process as commercial manufacturing. The spread and prolongation of the COVID-19 pandemic has led to a global decline in plant operating rates and a prioritization of supply of raw materials for the production of COVID-19 vaccines, resulting in a decline in volume and delays in the supply of the raw materials required for the Company's development and manufacturing of HGF. Accordingly, several trials that were scheduled to be

completed in the previous fiscal year have been rescheduled for completion in the current fiscal year.

For the purpose of identifying more effective administration methods and timing with recombinant human HGF for SCI, the Company launched a new joint research program with Keio University School of Medicine in February 2021 to investigate possible combination with the transplantation technology for iPS cell-derived neural progenitor cells. This joint research program continued in the three months ended December 31, 2021.

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).

(b) Amyotrophic lateral sclerosis (ALS)

The investigator-initiated Phase II clinical trial started in May 2016 at Tohoku University Hospital and Osaka University Hospital by Professor Masashi Aoki of the Department of Neurology, Tohoku University. In November 2020, the enrollment of patients was completed, and during the three months ended December 31, 2021, the final follow-up for the last patient was completed in December 2021. As the supplier of the investigational drug, the Company has continued to engage in the trial by supplying the investigational drug, supporting clinical trial operations, and performing the drug stability tests. The Company continued to perform the drug stability tests in the three months ended December 31, 2021.

In addition, during the three months ended December 31, 2021, the Company supported the clinical trial financially mainly covering the cost for contract research organization (CRO), in order to avoid a delay of the study due to the termination of subsidies provided by Japan Agency for Medical Research and Development (AMED) , a National Research and Development Agency, in March 2021.

In September 2021, Professor Masashi Aoki gave a presentation on the development of recombinant human HGF protein as a therapeutic agent for ALS at the Pan-Asian Consortium for Treatment and Research in ALS (PACTALS).

(c) 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.). A preliminary consultation meeting with PMDA was subsequently conducted in July 2019, based on which discussion is ongoing with Kyoto Prefectural University of Medicine to design details of the next phase trial (double-blind, placebo-controlled comparative study) aimed at obtaining POC, and the Company has formulated a plan to commence the study in the fiscal year ending September 2022.

In order to raise funds to finance clinical trials, the manufacturing of investigational drugs, and the development of commercial formulations, the Company issued share acquisition rights in November 2021, and is also working to utilize public funding, with its proposed research topic being selected for the Cyclic Innovation for Clinical Empowerment (CiCLE) project operated by the Japan Agency for Medical Research and Development (AMED).

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

The Company concluded a license and supply agreement with Claris Biotherapeutics, Inc. of the U.S. in April 2020 to supply HGF drug substance for clinical development by Claris Biotherapeutics to treat ophthalmologic diseases in the U.S.

The Company did not supply HGF drug substance to Claris Biotherapeutics during the three months ended December 31, 2021. Meanwhile, Claris Biotherapeutics 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 development, the Company will now receive a fixed annual technology access fee (royalty income).

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

2. Business development activities

During the three months ended December 31, 2021, the Company had business development discussion with potential business partners to expand development of acute SCI outside Japan.

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 main component of our development pipeline.

As a result of these efforts, during the three months ended December 31, 2021, net sales amounted to ¥13,800 thousand (a year-on-year decrease of 85.4%), while the Company recorded an operating loss of ¥120,154 thousand (operating loss during the three months ended December 31, 2020 was ¥45,602 thousand), ordinary loss of ¥128,638 (ordinary loss during the three months ended December 31, 2020 was ¥61,945 thousand) and loss of ¥129,010 thousand (loss during the three months ended December 31, 2020 was ¥62,317 thousand).

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

(2) Explanation of Financial Position

Assets, liabilities and net assets as of December 31, 2021

Assets

Current assets as of December 31, 2021 increased by ¥25,922 thousand from the end of the previous fiscal year to ¥2,660,516 thousand (a year-on-year increase of 1.0%). This was mainly due to an increase of ¥16,021 thousand in cash and deposits as a result of an increase in capital due to the exercise of share acquisition rights. Non-current assets increased by ¥1,083 thousand from the end of the previous fiscal year to ¥2,114 thousand (a year-on-year increase of 105.1%). This was mainly due to an increase of ¥1,083 thousand in investments and other assets.

As a result, total assets increased by ¥27,005 thousand from the end of the previous fiscal year to ¥2,662,630 thousand (a year-on-year increase of 1.0%).

Liabilities

Current liabilities as of December 31, 2021 increased by ¥1,356 thousand from the end of the previous fiscal year to ¥128,552 thousand (a year-on-year increase of 1.1%). This was mainly due to an increase of ¥10,558 thousand in accounts payable-other and an increase of ¥5,715 thousand in other, despite a decrease of ¥13,800 thousand in advances received. Non-current liabilities remained mostly the same as those at the end of the previous fiscal year, reporting an increase of ¥11 thousand to ¥2,290 thousand (a year-on-year increase of 0.5%).

As a result, total liabilities increased by ¥1,367 thousand from the end of the previous fiscal year to ¥130,843 thousand (a year-on-year increase of 1.1%).

Net assets

Net assets as of December 31, 2021 increased by ¥25,638 thousand from the end of the previous fiscal year to ¥2,531,787 thousand (a year-on-year increase of 1.0%) due to increases of ¥76,925 thousand in share capital and legal capital surplus, respectively, as a result of an increase in capital due to the exercise of share acquisition rights, despite a decrease of ¥129,010 thousand in retained earnings due to loss recorded.

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

There are no changes to the full-year financial results forecast for the fiscal year ending September 30, 2022, which was announced by the Company on November 12, 2021 in the “Financial Results for the Fiscal Year Ended September 30, 2021.”

2. Quarterly Financial Statements and Principal Notes
(1) Quarterly Balance Sheets

(Million yen)

	As of September 30, 2021	As of December 31, 2021
Assets		
Current assets		
Cash and deposits	2,137520	2,153,542
Accounts receivable - trade	6,717	—
	88,413	8,8413
Raw materials and supplies	226,681	227,478
Advance payments - trade	77,965	87,058
Consumption taxes receivable	76,684	87,406
Other	20,610	16,617
Total current assets	2,634,594	2,660,516
Non-current assets		
Property, plant and equipment	—	—
Investments and other assets	1,031	2,114
Total non-current assets	1,031	2,114
Total assets	2,635,625	2,662,630
Liabilities		
Current liabilities		
Accounts payable - other	30,968	41,526
Income taxes payable	1,490	372
Advances received	89,200	75,400
Other	5,538	11,253
Total current liabilities	127,196	128,552
Non-current liabilities		
Asset retirement obligations	2,278	2,290
Total non-current liabilities	2,278	2,290
Total liabilities	129,475	130,843
Net assets		
Shareholders' equity		
Share capital	51,820	128,745
Capital surplus	2,755,541	2,832,466
Retained earnings	(301,166)	(430,177)
Treasury shares	(45)	(45)
Total shareholders' equity	2,506,149	2,530,989
Share acquisition rights	—	798
Total net assets	2,506,149	2,531,787
Total liabilities and net assets	2,635,625	2,662,630

(2) Quarterly Statements of Income

Three Months Ended December 31

(Million yen)

	For the three months ended December 31, 2020	For the three months ended December 31, 2021
Net sales	94,230	13,800
Cost of sales	—	—
Gross profit	94,230	13,800
Selling, general and administrative expenses	139,832	133,954
Operating loss	(45,602)	(120,154)
Non-operating expenses		
Listing expenses	11,887	—
Share issuance costs	4,330	—
Share acquisition rights issuance costs	—	8,387
Exchange loss	124	96
Total non-operating expenses	16,342	8,484
Ordinary loss	(61,945)	(128,638)
Loss before income taxes	(61,945)	(128,638)
Income taxes - current	372	372
Total income taxes	372	372
Loss	(62,317)	(129,010)

(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 December31, 2020

Effective December 28, 2020, the Company was listed on the Tokyo Stock Exchange Mothers market. Upon the listing, share capital and capital surplus each increased by ¥266,800 thousand through the issuance of 580,000 shares of new shares by way of a public offering (book building method) with the payment date of December 27, 2020.

As a result, as of December 31, 2020, share capital and capital surplus amounted to ¥566,800 thousand and ¥2,920,802 thousand, respectively.

For the three months ended December31, 2021

On November 1, 2021, the Company allotted its 10th series of share acquisition rights to Barclays Bank PLC. Due to the exercise of share acquisition rights during the three months ended December 31, 2021, share capital and capital surplus increased by ¥76,925 thousand, respectively.

As a result, as of December 31, 2021, share capital and capital surplus amounted to ¥128,745 thousand and ¥2,832,466 thousand, respectively.

Changes in Accounting Policies

Application of Accounting Standard for Revenue Recognition, etc.

Effective the beginning of the first quarter under review, the Company has adopted the "Accounting Standard for Revenue Recognition"(ASBJ Statement No.29, March 31, 2020; "Revenue Recognition Accounting Standard") to recognize revenue at the amount it expects to receive in exchange for the promised goods or services when control of the aforementioned goods or services is transferred to the customer.

Regarding the application of the Revenue Recognition Accounting Standard and other standards, although the Company has followed the transitional treatment prescribed in the proviso of Paragraph 84 of the Revenue Recognition Accounting Standard, there is no impact on the opening balance of retained earnings brought forward as of October 1, 2021. In addition, there is no impact on profit and loss during the three months ended December 31, 2021.

In accordance with the transitional treatment prescribed in Paragraph 28-15 of the "Accounting Standard for Quarterly Financial Reporting" (ASBJ Statement No. 12, March 31, 2020), the Company has not listed information on the breakdown of revenues generated from contracts with customers for the three months ended December 31, 2020.

Application of Accounting Standard for Fair Value Measurement and Other Standards

Effective the beginning of the first quarter under review, the Company has adopted the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30, July 4, 2019; "Fair Value Measurement Accounting Standard") to apply the new accounting policies prescribed in the Fair Value Measurement Accounting Standard and other standards into the future, in accordance with the transitional treatment prescribed in Paragraph 19 of the Fair Value Measurement Accounting Standard and Paragraph 44-2 of the "Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, July 4, 2019). The above accounting treatment has no impact on the Company's quarterly financial statements.

Significant subsequent events

Exercise of share acquisition rights

During the period between January 1, 2022 and February 14, 2022, the 10th 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	2,287
2. Type and number of shares issued	228,700 common shares
3. Increase in share capital	¥69,592 thousand
4. Increase in legal capital surplus	¥69,592 thousand