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

May 15, 2023

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
Contact: Koichi Murakami, Member of the Board, Director of Corporate Planning Management
Phone: +81-72-641-8739

Scheduled date of filing quarterly securities report: May 15, 2023
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 Six Months Ended March 31, 2023 (October 1, 2022 - March 31, 2023)

(1) Operating Results

(% indicates changes from the previous corresponding period.)

	Net sales		Operating profit		Ordinary profit		Profit	
Six months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
March 31, 2023	34	25.8	(314)	–	(314)	–	(315)	–
March 31, 2022	27	(76.8)	(310)	–	(318)	–	(319)	–

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
March 31, 2023	(58.63)	–
March 31, 2022	(70.24)	–

(2) Financial Position

	Total assets	Net assets	Equity ratio
As of	Million yen	Million yen	%
March 31, 2023	2,871	2,480	86.1
September 30, 2022	3,208	2,789	86.8

Reference: Equity: As of March 31, 2023: ¥2,472 million As of September 30, 2022: ¥2,785 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, 2022	–	–	–	0.00	0.00
Fiscal year ending September 30, 2023	–	0.00			
Fiscal year ending September 30, 2023 (Forecast)			–	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, 2023 (October 1, 2022 - September 30, 2023)

(% 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	68	(82.4)	(993)	–	(953)	–	(955)	–	(177.44)

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 March 31, 2023:	5,390,700 shares
As of September 30, 2022:	5,380,700 shares

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

As of March 31, 2023:	87 shares
As of September 30, 2022:	87 shares

3) Average number of shares during the period:

For the six months ended March 31, 2023:	5,382,371 shares
For the six months ended March 31, 2022:	4,551,932 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.

Table of Contents - Attachments

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 second quarter under review.

In the Japanese pharmaceutical market during the six months ended March 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.

On the other hand, although the protracted COVID-19 pandemic 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, 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. 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 six months ended March 31, 2023, at the five medical facilities where patients are being enrolled.

* The last patient enrollment was completed on April 13, 2023.

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 previous fiscal year. Process validation of the drug product is still going according to plan.

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

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, in September 2022, Kringle and Keio University jointly filed a second patent application, having confirmed 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. 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 IIII 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 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 suppressed 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. When it comes to the direction of future development, the company plans to make a decision in cooperation with Tohoku University, based on the results of further detailed analysis.

(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 to treat ophthalmologic diseases in the U.S.

During the previous fiscal year, 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 six 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.

* 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 proteins by seeking new research proposals from researchers regarding the use of HGF proteins.

2. Business development activities

During the six months ended March 31, 2023, 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 drug substance of our development pipeline.

As a result of these efforts, during the six months ended March 31, 2023, net sales amounted to ¥34,353 thousand (a year-on-year increase of 25.8%), while the Company recorded an operating loss of ¥314,934 thousand (operating loss during the six months ended March 31, 2022 was ¥310,706 thousand), ordinary loss of ¥314,811 thousand (ordinary loss during the six months ended March 31, 2022 was ¥318,965 thousand) and loss of ¥315,557 thousand (loss during the six months ended March 31, 2022 was ¥319,710 thousand).

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

(2) Explanation of Financial Position

1. Assets, liabilities and net assets as of March 31, 2023

Assets

Current assets as of March 31, 2023 decreased by ¥337,533 thousand from the end of the previous fiscal year to ¥2,870,117 thousand (a decrease of 10.5% from the end of the previous fiscal year). This was mainly due to a decrease of ¥291,858 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 ¥1,040 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 ¥337,533 thousand from the end of the previous fiscal year to ¥2,871,157 thousand (a decrease of 10.5% from the end of the previous fiscal year).

Liabilities

Current liabilities as of March 31, 2023 decreased by ¥28,425 thousand from the end of the previous fiscal year to ¥134,399 thousand (a decrease of 17.5% from the end of the previous fiscal year). This was mainly due to a decrease of ¥31,455 thousand in advances received, which was partially offset by an increase of ¥4,951 thousand in accounts payable-other. Non-current liabilities amounted to ¥256,679 thousand, equaling the amount at the end of the previous fiscal year in the absence of any fluctuation in non-current liabilities from the end of the previous fiscal year.

As a result, total liabilities decreased by ¥28,425 thousand from the end of the previous fiscal year to ¥391,079 thousand (a decrease of 6.8% from the end of the previous fiscal year).

Net assets

Net assets as of March 31, 2023 decreased by ¥309,108 thousand from the end of the previous fiscal year to ¥2,480,078 thousand (a decrease of 11.1% from the end of the previous fiscal year). This primarily reflected a decrease of ¥315,557 thousand in retained earnings due to the recording of a net loss for the quarter, which was partially offset by increases of both share capital and legal capital surplus of ¥1,300 thousand each as a result of capital increase by way of execution of share acquisition rights.

This resulted in share capital of ¥61,177 thousand, capital surplus of ¥3,059,148 thousand, and negative retained earnings of ¥647,387 thousand.

2. Status of cash flows

Cash and cash equivalents (hereafter “cash”) as of March 31, 2023 were ¥2,089,311 thousand, a decrease of ¥412,734 thousand from the end of the previous fiscal year.

The status of cash flows for the six months ended March 31, 2023 was as follows.

Cash flows from operating activities

Net cash used in operating activities was ¥294,458 thousand (net cash used in operating activities during the same period the previous fiscal year was ¥150,244 thousand). This was mainly due to a loss before income taxes of ¥314,811 thousand, offsetting an increase in cash resulting from a decrease in accounts receivable-other of ¥43,864 thousand.

Cash flows from investing activities

Net cash used in investing activities was ¥120,875 thousand (net cash used in investing activities during the same period the previous fiscal year was ¥254,374 thousand). This was due to ¥120,875 thousand of payments into time deposits.

Cash flows from financing activities

Net cash provided by financing activities was ¥2,600 thousand (net cash provided by financing activities during the same period the previous fiscal year was ¥386,264 thousand). This was due to proceeds from issuance of shares resulting from exercise of share acquisition rights of ¥2,600 thousand.

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

The financial results forecast for the fiscal year ending September 30, 2023 (October 1, 2022 - September 30, 2023) is unchanged from the forecast announced in “Financial Results for the Fiscal Year Ended September 30, 2022” on November 14, 2022.

2. Quarterly Financial Statements and Principal Notes

(1) Quarterly Balance Sheets

(Thousand yen)

	As of September 30, 2022	As of March 31, 2023
Assets		
Current assets		
Cash and deposits	2,756,420	2,464,562
Raw materials and supplies	349,875	357,313
Advance payments to suppliers	19,173	12,942
Consumption taxes receivable	67,941	26,046
Other	14,239	9,252
Total current assets	3,207,651	2,870,117
Non-current assets		
Property, plant and equipment	–	–
Investments and other assets	1,040	1,040
Total non-current assets	1,040	1,040
Total assets	3,208,691	2,871,157
Liabilities		
Current liabilities		
Accounts payable - other	52,864	57,816
Income taxes payable	1,490	745
Advances received	101,911	70,456
Other	6,558	5,382
Total current liabilities	162,824	134,399
Non-current liabilities		
Asset retirement obligations	2,305	2,305
Long-term deposits received	254,374	254,374
Total non-current liabilities	256,679	256,679
Total liabilities	419,504	391,079
Net assets		
Shareholders' equity		
Share capital	59,877	61,177
Capital surplus	3,057,848	3,059,148
Retained earnings	(331,829)	(647,387)
Treasury shares	(75)	(75)
Total shareholders' equity	2,785,820	2,472,863
Share acquisition rights	3,366	7,215
Total net assets	2,789,187	2,480,078
Total liabilities and net assets	3,208,691	2,871,157

(2) Quarterly Statements of Income

Six Months Ended March 31

(Thousand yen)

	For the six months ended March 31, 2022	For the six months ended March 31, 2023
Net sales	27,300	34,353
Cost of sales	–	–
Gross profit	27,300	34,353
Selling, general and administrative expenses	338,006	349,287
Operating loss	(310,706)	(314,934)
Non-operating income		
Interest income	0	5
Subsidy income	–	100
Interest on tax refund	207	83
Other	31	0
Total non-operating income	239	188
Non-operating expenses		
Share acquisition rights issuance costs	8,387	–
Foreign exchange losses	109	65
Total non-operating expenses	8,497	65
Ordinary loss	(318,965)	(314,811)
Loss before income taxes	(318,965)	(314,811)
Income taxes - current	745	745
Total income taxes	745	745
Loss	(319,710)	(315,557)

(3) Quarterly Statements of Cash Flows

(Thousand yen)

	For the six months ended March 31, 2022	For the six months ended March 31, 2023
Cash flows from operating activities		
Loss before income taxes	(318,965)	(314,811)
Interest income	(0)	(5)
Share acquisition rights issuance costs	8,387	–
Subsidy income	–	100
Decrease (increase) in trade receivables	6,717	–
Decrease (increase) in inventories	(111,333)	(7,437)
Decrease (increase) in accounts receivable - other	39,413	43,864
Decrease (increase) in advance payments to suppliers	15,626	6,231
Decrease (increase) in prepaid expenses	4,341	2,916
Increase (decrease) in accounts payable - other	184,629	4,951
Increase (decrease) in advances received	(27,300)	(34,353)
Other	1,973	2,672
Subtotal	(196,509)	(295,870)
Interest received	0	5
Subsidies received	40,000	2,898
Income taxes paid	(1,490)	(1,490)
Income taxes refund	7,754	–
Net cash provided by (used in) operating activities	(150,244)	(294,458)
Cash flow from investing activities		
Payments into time deposits	(254,374)	(120,875)
Net cash provided by (used in) investing activities	(254,374)	(120,875)
Cash flows from financing activities		
Proceeds from issuance of share acquisition rights	1,070	–
Proceeds from issuance of shares resulting from exercise of share acquisition rights	385,224	2,600
Other	(30)	–
Net cash provided by (used in) financing activities	386,264	2,600
Effect of exchange rate change on cash and cash equivalents	–	–
Net increase (decrease) in cash and cash equivalents	(18,354)	(412,734)
Cash and cash equivalents at beginning of period	2,137,520	2,502,046
Cash and cash equivalents at end of period	2,119,165	2,089,311

(4) Notes to Quarterly Financial Statements

Notes on going concern assumption

Not applicable.

Notes in case of significant changes in shareholders' equity

For the six months ended March 31, 2022

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 six months ended March 31, 2022, share capital and capital surplus increased by ¥197,148 thousand and ¥197,147 thousand, respectively.

As a result, as of March 31, 2022, share capital and capital surplus amounted to ¥248,968 thousand and ¥2,952,689 thousand, respectively.

For the six months ended March 31, 2023

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	For the six months ended March 31, 2022	For the six months ended March 31, 2023
Lump-sum revenue from contracts	–	–
Milestone revenue	–	–
Royalty income	27,300	34,353
Revenue from product sales	–	–
Revenue from contracts with customers	27,300	34,353
Other revenue	–	–
Revenues from external customers	27,300	34,353