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# Financial Results for the Nine Months Ended June 30, 2023 [Japanese GAAP] (Non-consolidated)

August 14, 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: August 14, 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 Nine Months Ended June 30, 2023 (October 1, 2022 - June 30, 2023)

(1) Operating Results

(% indicates changes from the previous corresponding period.)

| | Net sales | | Operating profit | | Ordinary profit | | Profit | |
|---|---|---|---|---|---|---|---|---|
| Nine months ended | Million yen | % | Million yen | % | Million yen | % | Million yen | % |
| June 30, 2023 | 51 | (54.0) | (620) | – | (577) | – | (578) | – |
| June 30, 2022 | 112 | (4.9) | (383) | – | (305) | – | (306) | – |

| | Basic earnings per share | Diluted earnings per share |
|---|---|---|
| Nine months ended | Yen | Yen |
| June 30, 2023 | (107.45) | – |
| June 30, 2022 | (65.02) | – |

(2) Financial Position

| | Total assets | Net assets | Equity ratio |
|---|---|---|---|
| As of | Million yen | Million yen | % |
| June 30, 2023 | 2,834 | 2,220 | 78.0 |
| September 30, 2022 | 3,208 | 2,789 | 86.8 |

Reference: Equity: As of June 30, 2023: ¥2,209 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 | 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) | – | (177.35) |

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 June 30, 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 June 30, 2023: | 87 shares |
| As of September 30, 2022: | 87 shares |

3) Average number of shares during the period:

| | |
|---|---|
| For the nine months ended June 30, 2023: | 5,385,118 shares |
| For the nine months ended June 30, 2022: | 4,719,173 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 third quarter under review.

In the Japanese pharmaceutical market during the nine months ended June 30, 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, a total of five medical facilities conducted the Phase III clinical trial, and the enrollment of the last patients was completed in April 2023, by the end of the first nine months under review.

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 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 implement additional analysis including biomarker evaluation in cooperation with Tohoku University.

(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 nine 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 nine months ended June 30, 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 the above, net sales amounted to ¥51,529 thousand (down 54.0% year on year) during the nine months ended June 30, 2023, reflecting the absence of supply of drug substance. The Company recorded an operating loss of ¥620,487 thousand (compared to an operating loss of ¥383,107 thousand a year ago), an ordinary loss of ¥577,513 thousand (compared to an ordinary loss of ¥305,721 thousand a year ago) and a loss of ¥578,631 thousand (compared to a loss of ¥306,838 thousand a year ago).

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 June 30, 2023 decreased by ¥373,915 thousand from the end of the previous fiscal year to ¥2,833,735 thousand (a decrease of 11.7% from the end of the previous fiscal year). This was mainly due to a decrease of ¥374,466 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 ¥373,915 thousand from the end of the previous fiscal year to ¥2,834,775 thousand (a decrease of 11.7% from the end of the previous fiscal year).

Liabilities

Current liabilities as of June 30, 2023 increased by ¥73,878 thousand from the end of the previous fiscal year to ¥236,703 thousand (an increase of 45.4% from the end of the previous fiscal year). This was mainly due to an increase of ¥160,544 thousand in accounts payable-other, which was partially offset by a decrease of ¥91,529 thousand in advances received.

Non-current liabilities increased by ¥121,226 thousand from the end of the previous fiscal year to ¥377,906 thousand (an increase of 47.2% from the end of the previous fiscal year). This primarily reflected an increase of ¥120,875 thousand in long-term deposits received.

As a result, total liabilities increased by ¥195,105 thousand from the end of the previous fiscal year to ¥614,609 thousand (an increase of 46.5% from the end of the previous fiscal year).

Net assets

Net assets as of June 30, 2023 decreased by ¥569,021 thousand from the end of the previous fiscal year to ¥2,220,165 thousand (a decrease of 20.4% from the end of the previous fiscal year). This primarily reflected a decrease of ¥578,631 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 ¥910,461 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 June 30, 2023 |
|---|---|---|
| Assets | | |
| Current assets | | |
| Cash and deposits | 2,756,420 | 2,381,954 |
| Raw materials and supplies | 349,875 | 364,131 |
| Advance payments to suppliers | 19,173 | 21,481 |
| Consumption taxes receivable | 67,941 | 51,823 |
| Other | 14,239 | 14,345 |
| Total current assets | 3,207,651 | 2,833,735 |
| 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 | 2,834,775 |
| Liabilities | | |
| Current liabilities | | |
| Accounts payable - other | 52,864 | 213,409 |
| Income taxes payable | 1,490 | 1,117 |
| Advances received | 101,911 | 10,381 |
| Other | 6,558 | 11,795 |
| Total current liabilities | 162,824 | 236,703 |
| Non-current liabilities | | |
| Asset retirement obligations | 2,305 | 2,305 |
| Long-term accounts payable - other | – | 350 |
| Long-term deposits received | 254,374 | 375,250 |
| Total non-current liabilities | 256,679 | 377,906 |
| Total liabilities | 419,504 | 614,609 |
| Net assets | | |
| Shareholders' equity | | |
| Share capital | 59,877 | 61,177 |
| Capital surplus | 3,057,848 | 3,059,148 |
| Retained earnings | (331,829) | (910,461) |
| Treasury shares | (75) | (75) |
| Total shareholders' equity | 2,785,820 | 2,209,789 |
| Share acquisition rights | 3,366 | 10,376 |
| Total net assets | 2,789,187 | 2,220,165 |
| Total liabilities and net assets | 3,208,691 | 2,834,775 |

(2) Quarterly Statements of Income

Nine Months Ended June 30, 2023

(Thousand yen)

| | For the nine months ended June 30, 2022 | For the nine months ended June 30, 2023 |
|---|---|---|
| Net sales | 112,068 | 51,529 |
| Cost of sales | – | – |
| Gross profit | 112,068 | 51,529 |
| Selling, general and administrative expenses | 495,175 | 672,017 |
| Operating loss | (383,107) | (620,487) |
| Non-operating income | | |
| Interest income | – | 5 |
| Subsidy income | 80,000 | 43,048 |
| Foreign exchange gains | 5,535 | – |
| Interest on tax refund | 207 | 83 |
| Other | 31 | 0 |
| Total non-operating income | 85,774 | 43,136 |
| Non-operating expenses | | |
| Share acquisition rights issuance costs | 8,387 | – |
| Foreign exchange losses | – | 162 |
| Total non-operating expenses | 8,387 | 162 |
| Ordinary loss | (305,721) | (577,513) |
| Loss before income taxes | (305,721) | (577,513) |
| Income taxes - current | 1,117 | 1,118 |
| Total income taxes | 1,117 | 1,118 |
| Loss | (306,838) | (578,631) |

## (3) Notes to Quarterly Financial Statements

**Notes on going concern assumption**

Not applicable.

**Notes in case of significant changes in shareholders' equity**

For the nine months ended June 30, 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 nine months ended June 30, 2022, share capital and capital surplus increased by ¥255,888 thousand and ¥255,888 thousand, respectively.

As a result, as of June 30, 2022, share capital and capital surplus amounted to ¥307,708 thousand and ¥3,011,429 thousand, respectively.

For the nine months ended June 30, 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 nine months ended June 30, 2022 | For the nine months ended June 30, 2023 |
|---|---|---|
| Lump-sum revenue from contracts | – | – |
| Milestone revenue | – | – |
| Royalty income | 40,950 | 51,529 |
| Revenue from product sales | 71,118 | – |
| Revenue from contracts with customers | 112,068 | 51,529 |
| Other revenue | – | – |
| Revenues from external customers | 112,068 | 51,529 |