Financial Results for the Nine Months Ended June 30, 2021
[Japanese GAAP]
(Non-consolidated)

August 13, 2021

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: August 13, 2021
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, 2021 (October 1, 2020 - June 30, 2021)

(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, 2021	117	91.4	(304)	—	(245)	—	(246)	—
June 30, 2020	61	—	(222)	—	(166)	—	(167)	—

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
June 30, 2021	(60.13)	—
June 30, 2020	(160.57)	—

Note: 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 June 30, 2021	2,619	2,557	97.6
As of September 30, 2020	2,350	2,188	93.1

Reference: Equity: As of June 30, 2021: ¥2,557 million
As of September 30, 2020: ¥2,188 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, 2020	—	—	—	0.00	0.00
Fiscal year ending September 30, 2021	—	—	0.00		
Fiscal year ending September 30, 2021 (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, 2021 (October 1, 2020 - September 30, 2021)

(% 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	227	(40.7)	(388)	—	(328)	—	(330)	—	(80.67)

Note: Revision to the financial results forecast announced most recently: Yes

*** 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, 2021: 4,320,700 shares
As of September 30, 2020: 3,647,700 shares

2) Total number of treasury shares at the end of the period:
As of June 30, 2021: — shares
As of September 30, 2020: — shares

3) Average number of shares during the period:
For the nine months ended June 30, 2021: 4,095,854 shares
For the nine months ended June 30, 2020: 1,041,060 shares

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, 2020.

* 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 third quarter under review.

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 next Phase III clinical trial to verify the proof of concept (POC; a preliminary evidence of efficacy detected in human 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 is now ongoing 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 conducting various tests related to the process of manufacturing recombinant human HGF. Trial manufacturing (process validation) is currently underway for the drug substance, which is required for the submission, using the same process as commercial manufacturing.

For the purpose of identifying more effective administration methods and schedule 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 technique for iPS cell-derived neural progenitor cells.

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 completed and the administration of the investigational drug is now continuing. The Company engages in the trial by supplying the investigational drug, supporting clinical trial operations, and performing the drug stability tests which were conducted during the nine months ended June 30, 2021.

In addition, during the nine months ended June 30, 2021, the Company continued to support 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) in March 2021.

(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 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.*). Preliminary consultation meeting with PMDA was 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. The Company has also continued to try acquiring grants or subsidies to fund the trial.

(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. During the nine months ended June 30, 2021, the Company's supply of HGF drug substance to Claris Biotherapeutics was continued for use in manufacturing the investigational product and conducting preclinical studies. Claris Biotherapeutics filed an investigational new drug (IND) application* in May 2021 to initiate a Phase I/II clinical trial utilizing the various preclinical and clinical information related to HGF provided by the Company.

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

2. Business development activities

During the nine months ended June 30, 2021, the Company had business development discussion with potential business partners to expand development of acute SCI outside Japan. In an effort to promote development of VFS, the Company also investigated a possibility to fund the project through partnership and/or subsidies.

As a result of these efforts, during the nine months ended June 30, 2021, net sales amounted to ¥117,825 thousand, while the Company recorded an operating loss, ordinary loss and loss of ¥304,865 thousand, ¥245,177 thousand, and ¥246,295 thousand, respectively.

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 June 30, 2021

Assets

Current assets as of June 30, 2021 increased by ¥269,118 thousand or 11.5% from the end of the previous fiscal year to ¥2,618,330 thousand. This was mainly due to an increase of ¥126,762 thousand in cash and deposits and an increase of ¥177,069 thousand in raw materials and supplies for manufacturing and development. Non-current assets remained the same as those at the end of the previous fiscal year at ¥1,031 thousand.

As a result, total assets increased by ¥269,118 thousand or 11.5% from the end of the previous fiscal year to ¥2,619,361 thousand.

Liabilities

Current liabilities as of June 30, 2021 decreased by ¥99,819 thousand or 62.6% from the end of the previous fiscal year to ¥59,667 thousand. This was mainly due to a decrease of ¥16,863 thousand in accounts payable-other primarily as a result of the completion of payment of contract manufacturing expenses which was posted in the previous fiscal year, and a decrease of ¥81,088 thousand in advances received due to the finalization of the research grant for orphan drugs allocated to development costs of recombinant human HGF for acute SCI. Non-current liabilities remained mostly the same as those at the end of the previous fiscal year, reporting an increase of ¥32 thousand or 1.5% to ¥2,267 thousand.

As a result, total liabilities decreased by ¥99,786 thousand or 61.7% from the end of the previous fiscal year to ¥61,935 thousand.

Net assets

Net assets as of June 30, 2021 increased by ¥368,904 thousand or 16.9% from the end of the previous fiscal year to ¥2,557,426 thousand. This was mainly due to increases in share capital and legal capital surplus by ¥307,600 thousand, respectively, in line with the capital increase upon the listing of the Company's shares on the Tokyo Stock Exchange Mothers market, despite the decrease of ¥246,295 thousand in retained earnings as a result of recording a loss.

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

In light of the financial results for the nine months ended June 30, 2021 and the future outlook, the Company has revised its financial results forecast for the full year, which was announced in the "Notice of Financial Information, etc., of Kringle Pharma, Associated with Its Listing on the Tokyo Stock Exchange Mothers Market," on December 28, 2020.

For details, see "Revision of the Financial Results Forecast" announced today (August 13, 2021).

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

(Million yen)

	As of September 30, 2020	As of June 30, 2021
Assets		
Current assets		
Cash and deposits	2,102,538	2,229,301
Accounts receivable - trade	105,810	—
Work in process	—	8,354
Raw materials and supplies	46,367	223,436
Advance payments - trade	59,195	79,168
Consumption taxes receivable	23,914	59,343
Other	11,385	18,724
Total current assets	2,349,211	2,618,330
Non-current assets		
Property, plant and equipment	—	—
Investments and other assets	1,031	1,031
Total non-current assets	1,031	1,031
Total assets	2,350,242	2,619,361
Liabilities		
Current liabilities		
Accounts payable - other	57,053	40,190
Income taxes payable	16,998	1,117
Advances received	81,088	—
Other	4,346	18,359
Total current liabilities	159,486	59,667
Non-current liabilities		
Asset retirement obligations	2,234	2,267
Total non-current liabilities	2,234	2,267
Total liabilities	161,721	61,935
Net assets		
Shareholders' equity		
Share capital	300,000	607,600
Capital surplus	2,654,002	2,961,602
Retained earnings	(765,481)	(1,011,776)
Total shareholders' equity	2,188,521	2,557,426
Total net assets	2,188,521	2,557,426
Total liabilities and net assets	2,350,242	2,619,361

(2) Quarterly Statements of Income

Nine Months Ended June 30

(Million yen)

	For the nine months ended June 30, 2020	For the nine months ended June 30, 2021
Net sales	61,566	117,825
Cost of sales	—	—
Gross profit	61,566	117,825
Selling, general and administrative expenses	284,490	422,691
Operating loss	(222,923)	(304,865)
Non-operating income		
Subsidy income	62,236	82,236
Other	1,117	341
Total non-operating income	63,354	82,578
Non-operating expenses		
Listing expenses	—	16,282
Share issuance costs	6,004	6,607
Other	472	—
Total non-operating expenses	6,477	22,890
Ordinary loss	(166,046)	(245,177)
Loss before income taxes	(166,046)	(245,177)
Income taxes - current	1,117	1,117
Total income taxes	1,117	1,117
Loss	(167,163)	(246,295)

(3) Notes to Quarterly Financial Statements

Notes on going concern assumption

Not applicable.

Notes in case of significant changes in shareholders' equity

Effective December 28, 2020, the Company was listed on the Tokyo Stock Exchange Mothers market. Upon the listing, share capital and legal 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.

Additionally, the Company's total number of issued and outstanding shares increased by 87,000 shares and share capital and legal capital surplus each increased by ¥40,020 thousand through the issuance of new shares through third-party allotment in connection with the offering by way of over-allotment with the payment date of January 26, 2021.

As a result, as of June 30, 2021, share capital and capital surplus amounted to ¥607,600 thousand and ¥2,961,602 thousand, respectively.

Significant subsequent events

Reduction of share capital and legal capital surplus, and appropriation of surplus

At the Extraordinary General Meeting of Shareholders held on June 10, 2021, the Company resolved on the "reduction of share capital and legal capital surplus and appropriation of surplus," which took effect on July 13, 2021.

1. Purpose of the reduction of share capital and legal capital surplus and appropriation of surplus

The Company posted a deficit of ¥765,481 thousand in retained earnings at the end of the previous fiscal year.

Accordingly, in order to improve the financial position of the Company, while also securing greater flexibility in its future capital policy including return to shareholders, as well as mitigating the tax burden, pursuant to the provisions of Article 447, Paragraph 1 and Article 448, Paragraph 1 of the Companies Act, the Company will reduce share capital and legal capital surplus and transfer the reduction to other capital surplus, and offset the deficit in retained earnings by transferring the increased other capital surplus to retained earnings pursuant to the provisions of Article 452 of the Companies Act.

2. Details of the reduction of share capital

(1) Amount of share capital to be reduced

Pursuant to the provisions of Article 447, Paragraph 1 of the Companies Act, share capital of ¥607,600 thousand as of March 31, 2021 will be reduced by ¥557,600 thousand to ¥50,000 thousand.

(2) Method of reduction of share capital

The amount of share capital will be reduced and transferred to other capital surplus.

3. Details of the reduction of legal capital surplus

(1) Amount of legal capital surplus to be reduced

Pursuant to the provisions of Article 448, Paragraph 1 of the Companies Act, legal capital surplus of ¥2,397,560 thousand as of March 31, 2021 will be reduced by ¥207,881 thousand to ¥2,189,678 thousand.

(2) Method of reduction of legal capital surplus

The amount of legal capital surplus will be reduced and transferred to other capital surplus.

4. Details of the appropriation of surplus

Pursuant to the provisions of Article 452 of the Companies Act, and provided that the reductions of the amount of share capital and legal capital surplus described in paragraphs 2 and 3 above, respectively, take effect, other

capital surplus of ¥765,481 thousand that increased as a result of these reductions will be fully transferred to retained earnings to offset the deficit.

(1) The item of surplus to be reduced and its amount
Other capital surplus: ¥765,481 thousand

(2) The item of surplus to be increased and its amount
Retained earnings: ¥765,481 thousand

5. Schedule of the reduction of share capital and legal capital surplus and appropriation of surplus

(1)	Resolution by the Board of Directors	May 21, 2021
(2)	Resolution by the General Meeting of Shareholders	June 10, 2021
(3)	Announcement to creditors for submitting their objections	June 11, 2021
(4)	Deadline for creditors' objections	July 12, 2021
(5)	Effective date for the capital reduction	July 13, 2021