Financial Results for the Fiscal Year Ended September 30, 2021 [Japanese GAAP] (Non-consolidated)

November 12, 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 the Annual General Meeting of Shareholders: December 24, 2021
Scheduled date of filing securities report: December 27, 2021
Scheduled date of commencing dividend payments: -
Availability of supplementary explanatory materials on quarterly financial results: Available
Schedule of financial results briefing session: Scheduled

(Amounts of less than one million yen are rounded down.)

1. Financial Results for the Fiscal Year Ended September 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	
Fiscal Year ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
September 30, 2021	289	(38.0)	(357)	—	(299)	—	(301)	—
September 30, 2020	467	—	(171)	—	(116)	—	(117)	—

	Basic earnings per share	Diluted earnings per share	Return on equity	Ordinary income to total assets	Operating income to net sales
Fiscal Year ended	Yen	Yen	%	%	%
September 30, 2021	(72.51)	—	(12.8)	(12.0)	(123.5)
September 30, 2020	(106.70)	—	(9.8)	(8.9)	(36.7)

Reference: Equity earnings (losses) of affiliates: Fiscal year ended September 30, 2021: ¥ — million
Fiscal year ended September 30, 2020: ¥ — million

Note:1. Although potential shares existed, diluted earnings per share are not shown, as a net loss per share was recorded.
2. We conducted a 20-for-1 share split on November 12, 2020. Basic earnings per share are calculated as if the share split had taken place at the beginning of the fiscal year ended September 30, 2020.

(2) Financial Position

	Total assets	Net assets	Equity ratio	Net assets per share
Fiscal Year ended	Million yen	Million yen	%	Yen
September 30, 2021	2,635	2,506	95.1	578.17
September 30, 2020	2,350	2,188	93.1	599.97

Reference: Equity: Fiscal year ended September 30, 2021: ¥2,506 million
Fiscal year ended September 30, 2020: ¥2,188 million

Note: We conducted a 20-for-1 share split on November 12, 2020. Basic earnings per share are calculated as if the share split had taken place at the beginning of the fiscal year ended September 30, 2020.

(3) Cash flows

	Cash flow from operating activities	Cash flow from investing activities	Cash flow from financing activities	Net assets per share
Fiscal Year ended	Million yen	Million yen	Million yen	Million yen
September 30, 2021	(560)	—	595	2,137
September 30, 2020	(146)	—	2,082	2,102

2. Dividends

	Annual dividends					Total dividends (Annual)	Dividend payout ratio	Dividends to net assets
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total			
	Yen	Yen	Yen	Yen	Yen	Million yen	%	%
Fiscal year ended September 30, 2020	—	—	—	0.00	0.00	—	—	—
Fiscal year ending September 30, 2021	—	0.00	—	0.00	0.00	—	—	—
Fiscal year ending September 30, 2022 (Forecast)	—	0.00	—	0.00	0.00		—	

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)

*** Notes:**

(1) 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

(2) 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 September 30, 2021: 4,334,700 shares
As of September 30, 2020: 3,647,700 shares

2) Total number of treasury shares at the end of the period:
As of September 30, 2021: 40 shares
As of September 30, 2020: — shares

3) Average number of shares during the period:
Fiscal year ended September 30, 2021: 4,153,592 shares
Fiscal year ended September 30, 2020: 1,104,320 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. Actual results may differ significantly from these forecasts due to various factors. Please refer to “1. Overview of Operating Results, etc. (4) Explanation of Financial Results Forecast and Other Forward-looking Information” on page 5 of the Attachments for the conditions on which financial results forecasts are based and the notes on the use of these forecasts.

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1. Overview of Operating Results, etc.

(1) Overview of Operating Results for the Fiscal Year Under Review

In the Japanese pharmaceutical market, substitution by generic drugs is progressing 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 cost of new drug increases to accommodate the growing scale of clinical trials, which accelerates alliance or M&A of pharmaceutical companies in Japan and overseas to expand their corporate scale. Within a company, R&D focuses on selected therapeutic areas of priority and such company is 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 pharmaceuticals resources are currently directed to development of vaccines and treatments for COVID-19, causing potential delay in clinical development of other drugs.

Amidst 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 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 and proceeding 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 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. 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 current fiscal year have been rescheduled for completion in the next 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.

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. As the supplier of the investigational drug, the Company has long worked to engage in the trial by supplying the investigational drug, supporting clinical trial operations, and performing the drug stability tests. The Company has continued to perform the drug stability tests in the current fiscal year.

In addition, during the current fiscal year, the Company has 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) 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 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 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 in the current fiscal year to commence the study in the fiscal year ending September 2022. In addition, in order to promote the development of the drug for this indication, the Company has continued to work to obtain subsidies, including applying for the 6th Cyclic Innovation for Clinical Empowerment (CiCLE) project sponsored 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. During the fiscal year, the Company's supply of HGF drug substance to Claris Biotherapeutics was continued for the use of 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 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.

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

2. Business development activities

During the fiscal year ended September 30, 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 the above, the business results for the current fiscal year are as follows.

Net sales during the fiscal year ended September 30, 2021 were ¥289,756 thousand (¥467,616 thousand during the previous fiscal year, a year-on-year decrease of ¥177,860 thousand or 38.0%). This was due to sales of drug substances supplied to Claris Biotherapeutics and technology access fees.

Cost of sales during the fiscal year ended September 30, 2021 was ¥71,598 thousand (there was no cost of sales during the previous fiscal year). Until the previous fiscal year, the Company sold drug substances that had been recognized as research and development expenses in previous years. However, from the current fiscal year, the commencement of cost accounting for drug substances has resulted in cost of sales being recognized.

Selling, general and administrative expenses during the fiscal year ended September 30, 2021 totaled ¥576,038 thousand (¥639,219 thousand during the previous fiscal year, a year-on-year decrease of ¥63,181 thousand or 9.9%). Research and development expenses included in selling, general and administrative expenses were ¥398,518 thousand (¥489,508 thousand during the previous fiscal year, a year-on-year decrease of ¥90,990 thousand or 18.6%). Research and development expenses included ¥71,457 thousand related to the ALS pipeline (¥32,704 thousand during the previous fiscal year, a year-on-year increase of ¥38,753 thousand or 118.5%), ¥153,448 thousand related to the SCI pipeline (¥300,662 thousand during the previous fiscal

year, a year-on-year decrease of ¥147,214 thousand or 49.0%), ¥115,647 thousand related to GMP manufacturing common to both pipelines (¥109,856 thousand during the previous fiscal year, a year-on-year increase of ¥5,790 thousand or 5.3%), and other research and development expenses of ¥57,966 thousand (¥46,286 thousand during the previous fiscal year, a year-on-year decrease of ¥11,679 thousand or 25.2%). Selling, general and administrative expenses are the sum of research and development expenses and other general and administrative expenses. Other general and administrative expenses totaled ¥177,520 thousand (¥149,710 thousand during the previous fiscal year, a year-on-year increase of ¥27,808 thousand or 18.6%).

Despite a decrease in selling, general and administrative expenses, the Company recorded an operating loss of ¥357,880 thousand (compared to an operating loss of ¥171,603 thousand during the previous fiscal year) due to a decrease in net sales against the previous fiscal year and occurrence of cost of sales.

Non-operating income during the fiscal year ended September 30, 2021 was ¥82,293 thousand, an increase of ¥18,938 thousand compared to the previous fiscal year. This was mainly due to an increase in subsidy income. Non-operating expenses during the fiscal year ended September 30, 2021, were ¥24,090 thousand, an increase of ¥15,996 thousand compared to the previous fiscal year. This was mainly due to recording ¥16,282 thousand listing expenses.

As a result of the above, ordinary loss during the fiscal year ended September 30, 2021 was ¥299,676 thousand (ordinary loss during the previous fiscal year was ¥116,341 thousand), and loss was ¥301,166 thousand (loss during the previous fiscal year was ¥117,831 thousand).

Since the Company operates in a single segment of pharmaceutical development business, segment information is not listed.

(2) Explanation of Financial Position

(Assets)

Current assets as of September 30, 2021 increased by ¥285,382 thousand from the end of the previous fiscal year to ¥2,634,594 thousand. This was mainly due to the manufacture of ¥88,413 thousand merchandise and finished goods for purpose of selling drug substances, and an increase of ¥180,314 thousand in raw materials and supplies for the purpose of conducting research and development of future drug substance formulations.

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 ¥285,382 thousand from the end of the previous fiscal year to ¥2,635,625 thousand.

(Liabilities)

Current liabilities as of September 30, 2021 decreased by ¥32,289 thousand from the end of the previous fiscal year to ¥127,196 thousand. This was mainly due to a decrease of ¥26,085 thousand in accounts payable-other as a result of progress in drug substance manufacturing, among other factors. Non-current liabilities remained mostly the same as those at the end of the previous fiscal year, reporting an increase to ¥2,278 thousand.

As a result, total liabilities decreased by ¥32,245 thousand from the end of the previous fiscal year to ¥129,475 thousand.

(Net assets)

Net assets as of September 30, 2021 increased by ¥317,628 thousand from the end of the previous fiscal year to ¥2,506,149 thousand. This was mainly due to increases in share capital and legal capital surplus by ¥306,820 thousand, respectively, in line with the capital increase upon the listing of the Company's shares and increases in share capital and legal capital surplus by ¥2,600 thousand, respectively, as a result of the exercise of share acquisition rights, despite loss of ¥301,166 thousand recorded during the fiscal year ended September 30, 2021. In addition, due to a reduction in the amount of share capital and legal capital surplus in July 2021, share capital and legal capital surplus were reduced by ¥557,600 thousand and ¥207,881 thousand, respectively, and these amounts were transferred to other capital surplus. In addition, the increase of ¥765,481 thousand in other capital surplus due to the above transfer was transferred to retained earnings brought forward in order to compensate for the deficit in retained earnings brought forward.

As a result, share capital was ¥51,820 thousand, capital surplus was ¥2,755,541 thousand yen, and retained earnings were -¥301,166 thousand.

(3) Overview of Cash Flows for the Fiscal Year Under Review

Cash and cash equivalents (hereafter "cash") at the end of the fiscal year ended September 30, 2021 were ¥2,137,520 thousand, an increase of ¥34,981 thousand from the end of the previous fiscal year.

The status of cash flows for the fiscal year ended September 30, 2021 is as follows:

(Cash Flows from Operating Activities)

Net cash used in operating activities during the fiscal year ended September 30, 2021 was ¥560,922 thousand. This was mainly

due to a loss before income taxes of ¥299,676 thousand and an increase in inventories of ¥268,727 thousand, despite subsidies received of ¥87,000 thousand.

(Cash Flows from Investing Activities)

There was no cash flow from investing activities during the fiscal year ended September 30, 2021.

(Cash Flows from Financing Activities)

Net cash provided by financing activities during the fiscal year ended September 30, 2021 was ¥595,904 thousand. This was due to proceeds from issuance of shares of ¥612,232 thousand and payment of ¥16,282 thousand for listing expenses.

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

(a) Net sales

For the fiscal year ended September 30, 2021, the Company recorded net sales from the supply of recombinant human HGF protein (KP-100) drug substance based on the license and supply agreement concluded with Claris Biotherapeutics in the ophthalmologic diseases field, and from the receipt of technology access fees (fixed amount) from Claris Biotherapeutics, which the Company receives annually starting from the first dose in the first clinical trial conducted by Claris Biotherapeutics. For the fiscal year ending September 30, 2022, the Company expects to continue to earn revenues from the supply of the drug substance and receipt of technology access fees.

As a result of the above, net sales for the fiscal year ending September 30, 2022 are projected to be ¥355 million (a year-on-year increase of 22.6%).

(b) Operating loss

In the fiscal year ended September 30, 2021, the Company recognized, as cost of sales, the manufacturing cost of drug substances supplied to Claris Biotherapeutics in the U.S. For the fiscal year ending September 30, 2022, the Company will continue to calculate the manufacturing cost of the drug substance per unit weight based on the past drug substance manufacturing records and multiply this by the estimated supply volume to Claris Biotherapeutics. Based on the projected supply volume to the Claris Biotherapeutics, the Company expects to recognize cost of sales of ¥138 million (a year-on-year increase of 93.5%).

Selling, general and administrative expenses are composed of research and development expenses and other general and administrative expenses.

Research and development expenses are projected to be ¥1,325 million for the fiscal year ending September 30, 2022, compared to ¥398 million for the fiscal year ended September 30, 2021 (a year-on-year increase of 232.6%). The breakdown of projected research and development expenses is as follows:

1) Research and development expenses for the acute SCI pipeline during the fiscal year ending September 30, 2022 are projected to be ¥250 million (a year-on-year increase of 63.0%), compared to ¥153 million during the fiscal year ended September 30, 2021, based on estimates for expenses related to Phase III clinical trials obtained from contract research organizations (CROs) and actual past costs of Phase I/II clinical trials.
2) Research and development expenses for the ALS pipeline during the fiscal year ending September 30, 2022 are projected to be ¥97 million (a year-on-year increase of 36.7%), compared to ¥71 million during the fiscal year ended September 30, 2021, based on estimates obtained from Tohoku University for the period from April 2021 through to the end of Phase II clinical trials, allocated to each fiscal year, as well as the expenses for using trial data, etc., calculated based on actual costs in current fiscal years.
3) For research and development expenses for the VFS pipeline, the Company started budgeting an additional ¥151 million from the fiscal year ending September 30, 2022 (¥- million during the current fiscal year), based on estimates from contract research organizations (CROs) and other related entities.
4) Research and development expenses for GMP manufacturing common to the therapeutic areas of acute SCI, ALS and VFS are projected to total ¥709 million during the fiscal year ending September 30, 2022 (a year-on-year increase of 513.7%), compared to ¥115 million during the fiscal year ended September 30, 2021, based on the GMP manufacturing schedule and manufacturing cost/lot estimates prepared by the Company's Pharmaceutical Development, as well as cost estimates for trials by business partners. These expenses were estimated as the costs related to the trials and manufacturing of drug substances planned by the Company to achieve drug substance formulations. Estimates of manufacturing cost/lot are projected based on past manufacturing performance.
5) Other research and development expenses, which consist of personnel costs in the Pharmaceutical Development and the

Quality Assurance as well as other miscellaneous expenses such as communication and travel expenses, are projected to be ¥116 million for the fiscal year ending September 30, 2022 (a year-on-year increase of 101.7%), compared to ¥57 million for the fiscal year ended September 30, 2021. Personnel costs for the Pharmaceutical Development and the Quality Assurance are projected based on the Company's personnel plan, taking into account salary increases, while other miscellaneous expenses such as communication and travel expenses are projected based on past results.

6) Other general and administrative expenses, which consist primarily of remuneration for officers and personnel expenses for organizations other than the Pharmaceutical Development, as well as rental expenses on land and buildings and fee expenses, are projected to be ¥248 million during the fiscal year ending September 30, 2022 (a year-on-year increase of 40.2%), compared to ¥177 million during the fiscal year ended September 30, 2021. Remuneration for officers and personnel expenses for employees are projected based on the Company's personnel plan, taking into account salary increases, while other general and administrative expenses such as rental expenses on land and buildings and fee expenses are projected based on past results.

As a result of the above, cost of sales during the fiscal year ending September 30, 2022 is projected to be ¥138 million (a year-on-year increase of 93.5%), selling, general and administrative expenses are projected to be ¥1,574 million (a year-on-year increase of 173.3%), and operating loss is projected to be ¥1,357 million (compared to an operating loss of ¥357 million during the current fiscal year).

(c) Ordinary loss

Non-operating income during the fiscal year ending September 30, 2022 is projected to be ¥80 million (a year-on-year decrease of 2.8%), compared to ¥82 million for the fiscal year ended September 30, 2021. The breakdown is projected to be income of ¥80 million, primarily based on actual subsidy income of ¥82 million for the acute SCI pipeline received during the fiscal year ended September 30, 2020.

Non-operating expenses during the fiscal year ending September 30, 2022 are projected to be ¥17 million (a year-on-year decrease of 26.4%), compared to ¥24 million during the fiscal year ended September 30, 2021, consisting primarily of share acquisition rights issuance costs and share issuance costs based on estimates from securities companies, printing companies, and legal counsel, among others.

As a result of the above, an ordinary loss of ¥1,295 million is projected for the fiscal year ending September 30, 2022 (compared to an ordinary loss of ¥299 million during the current fiscal year).

(d) Net loss

There are no extraordinary income or losses projected as of the date of preparation of this forecast.

As a result of the above, a loss of ¥1,297 million is projected for the fiscal year ending September 30, 2022 (compared to a loss of ¥301 million during the current fiscal year).

2. Basic Policy in Selection of Accounting Standard

As the Company does not prepare consolidated financial statements, financial statements are prepared in accordance with Japanese GAAP, considering the burden of preparing systems to enable the preparation of financial statements in accordance with International Financial Reporting Standards, among other matters.

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

(Thousand yen)

	As of September 30, 2020	As of September 30, 2021
Assets		
Current assets		
Cash and deposits	2,102,538	2,137,520
Accounts receivable - trade	105,810	6,717
Merchandise and finished goods	-	88,413
Raw materials and supplies	46,367	226,681
Advance payments to suppliers	59,195	77,965
Prepaid expenses	4,042	12,856
Consumption taxes receivable	23,914	76,684
Other	7,343	7,754
Total current assets	2,349,211	2,634,594
Non-current assets		
Property, plant and equipment	-	-
Investments and other assets		
Guarantee deposits	1,031	1,031
Total investments and other assets	1,031	1,031
Total non-current assets	1,031	1,031
Total assets	2,350,242	2,635,625
Liabilities		
Current liabilities		
Accounts payable - other	57,053	30,968
Accrued expenses	2,520	3,049
Income taxes payable	16,998	1,490
Advances received	81,088	89,200
Deposits received	1,825	2,489
Total current liabilities	159,486	127,196
Non-current liabilities		
Asset retirement obligations	2,234	2,278
Total non-current liabilities	2,234	2,278
Total liabilities	161,721	129,475
Net assets		
Shareholders' equity		
Share capital	300,000	51,820
Capital surplus		
Legal capital surplus	2,089,960	2,191,498
Other capital surplus	564,042	564,042
Total capital surplus	2,654,002	2,755,541
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(765,481)	(301,166)
Total retained earnings	(765,481)	(301,166)
Treasury shares	-	(45)
Total shareholders' equity	2,188,521	2,506,149
Total net assets	2,188,521	2,506,149
Total liabilities and net assets	2,350,242	2,635,625

(2) Statements of Income

(Thousand yen)

	For the fiscal ended September 30, 2020	For the fiscal ended September 30, 2021
Net sales	467,616	289,756
Cost of sales	-	71,598
Gross profit	467,616	218,157
Selling, general and administrative expenses	639,219	576,038
Operating loss	(171,603)	(357,880)
Non-operating income		
Interest income	0	1
Subsidy income	62,236	82,236
Other	1,118	56
Total non-operating income	63,355	82,293
Non-operating expenses		
Listing expenses	-	16,282
Share issuance costs	7,436	6,607
Foreign exchange losses	657	1,030
Other	-	168
Total non-operating expenses	8,093	24,090
Ordinary loss	(116,341)	(299,676)
Loss before income taxes	(116,341)	(299,676)
Income taxes - current	1,490	1,490
Total income taxes	1,490	1,490
Loss	(117,831)	(301,166)

(3) Statements of Changes in Net Assets

For the fiscal year ended September 30, 2020 (From October 1, 2019 to September 30, 2020)

(Thousand yen)

	Shareholders' equity			
	Share capital	Capital surplus		
		Legal capital surplus	Other capital surplus	Total capital surplus
Balance at beginning of period	100,000	200,000	564,042	764,042
Changes during period				
Issuance of new shares	1,044,980	1,044,980		1,044,980
Capital reduction	(844,980)	844,980		844,980
Net loss				
Total changes during period	200,000	1,889,960	-	1,889,960
Balance at end of period	300,000	2,089,960	564,042	2,654,002

	Shareholders' equity			Total net assets
	Retained earnings		Total shareholders' equity	
	Other retained earnings	Total retained earnings		
	Retained earnings brought forward			
Balance at beginning of period	(647,649)	(647,649)	216,393	216,393
Changes during period				
Issuance of new shares			2,089,960	2,089,960
Capital reduction			-	-
Net loss	(117,831)	(117,831)	(117,831)	(117,831)
Total changes during period	(117,831)	(117,831)	1,972,128	1,972,128
Balance at end of period	(765,481)	(765,481)	2,188,521	2,188,521

For the fiscal year ended September 30, 2021 (From October 1, 2020 to September 30, 2021)

(Thousand yen)

	Shareholders' equity			
	Share capital	Share capital		
		Legal capital surplus	Other capital surplus	Total capital surplus
Balance at beginning of period	300,000	2,089,960	564,042	2,654,002
Changes during period				
Issuance of new shares	306,820	306,820		306,820
Issuance of new shares - exercise of share acquisition rights	2,600	2,600		2,600
Capital reduction	(557,600)	(207,881)	765,481	557,600
Deficit disposition			(765,481)	(765,481)
Net loss				
Purchase of treasury shares				
Total changes during period	(248,180)	101,538	-	101,538
Balance at end of period	51,820	2,191,498	564,042	2,755,541

	Shareholders' equity				Total net assets
	Retained earnings		Treasury shares	Total shareholders' equity	
	Other retained earnings	Total retained earnings			
	Retained earnings brought forward				
Balance at beginning of period	(765,481)	(765,481)	-	2,188,521	2,188,521
Changes during period					
Issuance of new shares				613,640	613,640
Issuance of new shares - exercise of share acquisition rights				5,200	5,200
Capital reduction				—	—
Deficit disposition	765,481	765,481		—	—
Net loss	(301,166)	(301,166)		(301,166)	(301,166)
Purchase of treasury shares			(45)	(45)	(45)
Total changes during period	464,314	464,314	(45)	317,628	317,628
Balance at end of period	(301,166)	(301,166)	(45)	2,506,149	2,506,149

(4) Statements of Cash Flows

(単位：千円)

	For the fiscal ended September 30, 2020	For the fiscal ended September 30, 2021
Cash flows from operating activities		
Loss before income tax	(116,341)	(299,676)
Interest and dividend income	(0)	(1)
Share issuance costs	7,436	6,607
Listing expenses	-	16,282
Subsidy income	(62,236)	(82,236)
Decrease (increase) in trade receivables	(105,810)	99,093
Decrease (increase) in inventories	(27,203)	(268,727)
Decrease (increase) in accounts receivable - other)	1,375	20
Decrease (increase) in advance payments to suppliers	(21,729)	(18,770)
Decrease (increase) in prepaid expenses	(1,622)	(8,813)
Increase (decrease) in accounts payable - other	27,433	(41,593)
Increase (decrease) in advances received	45,828	3,372
Other	9,827	(51,989)
Subtotal	(243,041)	(646,433)
Interest and dividends received	0	1
Subsidies received	97,000	87,000
Income taxes paid	(420)	(1,490)
Net cash provided by (used in) operating activities	(146,461)	(560,922)
Cash flows from financing activities		
Proceeds from issuance of shares	2,082,523	612,232
Payment of listing expenses	-	(16,282)
Other	-	(45)
Net cash provided by (used in) financing activities	2,082,523	595,904
Net increase (decrease) in cash and cash equivalents	1,936,061	34,981
Cash and cash equivalents at beginning of period	166,476	2,102,538
Cash and cash equivalents at end of period	2,102,538	2,137,520

(5) Notes to Financial Statements

Notes on going concern assumption

Not applicable.

Segment information

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

Profit or loss under equity method, etc.

Not applicable.

Per-share information

	Previous fiscal year (October 1, 2019 to September 30, 2020)	Fiscal year under review (October 1, 2020 to September 30, 2021)
Net assets per share	¥599.97	¥578.17
Net loss per share	(¥106.70)	(¥72.51)

Notes: 1. Although potential shares existed, diluted earnings per share are not shown, as a net loss per share was recorded.

2. The Company conducted a 20-for-1 share split on November 12, 2020. Net assets per share and net loss per share are calculated as if the share split had taken place at the beginning of the fiscal year ended September 30, 2020.

3. The basis for the calculation of net loss per share is as follows.

Item	Previous fiscal year (October 1, 2019 to September 30, 2020)	Fiscal year under review (October 1, 2020 to September 30, 2021)
Net loss per share		
Loss (thousand yen)	(117,831)	(301,166)
Amount not attributable to common shareholders (thousand yen)	-	-
Loss on common shares (thousand yen)	(117,831)	(301,166)
Average number of common shares during the period (shares)	1,104,320	4,153,592
Overview of potential shares not included in the calculation of diluted earnings per share due to lack of dilutive effect	4 types of share acquisition rights (Number of share acquisition rights: 24,250) (Number of shares to be issued upon exercise of share acquisition rights: 485,000 shares)	4 types of share acquisition rights (Number of share acquisition rights: 23,100) (Number of shares to be issued upon exercise of share acquisition rights: 462,000 shares)

4. The basis for the calculation of net assets per share is as follows.

Item	Previous fiscal year (As of September 30, 2020)	Fiscal year under review (As of September 30, 2021)
Total net assets (thousand yen)	2,188,521	2,506,149
Amount deducted from total net assets (thousand yen)	-	-
Net assets related to common shares at the end of the period (thousand yen)	2,188,521	2,506,149

Number of common shares at the end of the period used for the calculation of net assets per share (shares)	3,647,700	4,334,660

Significant subsequent events

10th offering of share acquisition rights via third-party allotment

The Company's Board of Directors meeting, held on October 15, 2021, passed a resolution to conduct the 10th offering of share acquisition rights (hereafter "Share Acquisition Rights") via third-party allotment, and the Company implemented this allotment on November 1, 2021.

Overview of Share Acquisition Rights

(1) Allotment date	November 1, 2021
(2) Type of shares to be issued upon exercise of share acquisition rights	Common shares of the Company
(3) Number of share acquisition rights issued	10,000
(4) Issue price	¥107 per Share Acquisition Right (Total amount to be paid in for these Share Acquisition Rights: ¥1,070,000)
(5) Number of potential shares due to this issuance	Number of potential shares: 1,000,000 shares (100 shares per Share Acquisition Right) The number of potential shares is also 1,000,000 at the minimum exercise price (see (8) below).
(6) Amount of funds to be raised (estimated net proceeds)	¥880,070,000 (Note) (Breakdown) Amount raised through the issue of the Share Acquisition Rights: ¥1,070,000 Amount raised through the exercise of Share Acquisition Rights: ¥891,000,000 Estimated issuance costs (deducted): ¥12,000,000
(7) Capital incorporation	The maximum amount of increase in stated capital, etc., calculated in accordance with the provisions of Article 17 of the Regulation on Corporate Accounting, multiplied by 0.5. Any fraction of less than one yen resulting from this calculation shall be rounded up to the nearest yen.
(8) Exercise price and conditions for revision of exercise price	Initial exercise price: ¥891 There is no upper limit to the exercise price. The lower limit of the exercise price is ¥535 (hereafter "Minimum Exercise Price"). The exercise price will be revised on and after November 2, 2021 in the case where, on the day when the notice of exercise requests for the Share Acquisition Rights is made (hereafter the "Revision Date"), the amount equivalent to 93% of the closing price of the common stock of the Company in regular trading on the Tokyo Stock Exchange, Inc. on the trading day immediately preceding the Revision Date is higher or lower than the exercise price in effect immediately preceding the Revision Date (if there is no closing price on the day in question, the closing price on the trading day immediately preceding the day in question). However, if the exercise price after revision is less than the Minimum Exercise Price, the Minimum Exercise Price shall become the exercise price after revision.

(9) Exercise period	November 2, 2021 to November 1, 2023
(10) Subscription or allotment method	Third-party allotment
(11) Allottee	Barclays Bank PLC (Barclays Bank)
(12) Use of funds	The Company has entered into a third-party allotment agreement with a commitment clause (hereafter the "Third-Party Allotment Agreement") with Barclays Bank after the filing under the Financial Instruments and Exchange Act became effective. The Third-Party Allotment Agreement stipulates the following: - Commitment by Barclays Bank to exercise the Share Acquisition Rights - Suspension of the exercise of the Share Acquisition Rights by the Company - Prohibition of the disposal etc. of the securities in question by the Company (lock-up provision) In the Third-Party Allotment Agreement, Barclays Bank has also agreed not to transfer the Share Acquisition Rights without the approval of the Board of Directors of the Company to any party other than the affiliates of Barclays Bank (defined as direct or indirect subsidiaries and parent companies [including the most superordinate holding company] of such parties and direct or indirect subsidiaries of such parent companies).

Note: The amount of funds to be raised is the sum of the total amount to be paid for the Share Acquisition Rights plus the total amount of the value of assets to be paid upon exercise of the Share Acquisition Rights, minus estimated issuance costs. The total amount of the value of assets to be paid upon the exercise of the Share Acquisition Rights is the amount assuming that all Share Acquisition Rights are exercised at the initial exercise price. The amount of funds raised will increase or decrease in the event that the exercise price is revised or adjusted. In addition, the amount of funds raised will decrease in the event that the Share Acquisition Rights are not exercised within the exercise period or the Company cancels the acquired Share Acquisition Rights.

Matters concerning procurement of funds

On November 1, 2021, we received a notice that the Japan Agency for Medical Research and Development (AMED) has selected the research topic "Development of a therapeutic drug for refractory fibrosis using recombinant HGF protein" submitted by the Company for funding under the 6th open solicitation for the Cyclic Innovation for Clinical Empowerment (CiCLE) program. For details, an agreement is to be concluded with AMED after consultation with AMED.

If such an agreement is concluded with AMED in accordance with the aforementioned selection for the program, the Company will receive funding subject to future repayment in whole or in part. There is also the possibility that the Company may be required to provide a reasonable amount of collateral or other similar arrangements