Financial Results for the Fiscal Year Ended September 30, 2022 [Japanese GAAP] (Non-consolidated)

November 14, 2022

Company name: Kringle Pharma, Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4884
URL: https://www.kringle-pharma.com/en/
Representative: Kiichi Adachi, President & CEO
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Scheduled date of the Annual General Meeting of Shareholders: December 23, 2022
Scheduled date of commencing dividend payments: —
Scheduled date of filing securities report: December 26, 2022
Availability of supplementary explanatory materials on 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, 2022 (October 1, 2021 - September 30, 2022)

(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, 2022	391	35.2	(426)	–	(330)	–	(331)	–
September 30, 2021	289	(38.0)	(357)	–	(299)	–	(301)	–

	Basic earnings per share	Diluted earnings per share	Return on equity	Ordinary profit to total assets	Operating profit to net sales
Fiscal year ended	Yen	Yen	%	%	%
September 30, 2022	(68.33)	–	(12.5)	(11.3)	(108.8)
September 30, 2021	(72.51)	–	(12.8)	(12.0)	(123.5)

Reference: Equity earnings (losses) of affiliates: Fiscal year ended September 30, 2022: ¥ — million
Fiscal year ended September 30, 2021: ¥ — million

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	Net assets per share
As of	Million yen	Million yen	%	Yen
September 30, 2022	3,208	2,789	86.8	517.75
September 30, 2021	2,635	2,506	95.1	578.17

Reference: Equity: As of September 30, 2022: ¥2,785 million As of September 30, 2021: ¥2,506 million

(3) Cash Flows

	Cash flows from operating activities	Cash flow from investing activities	Cash flows from financing activities	Cash and cash equivalents at end of period
Fiscal year ended	Million yen	Million yen	Million yen	Million yen
September 30, 2022	15	(254)	603	2,502
September 30, 2021	(560)	–	595	2,137

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, 2021	–	0.00	–	0.00	0.00	–	–	–
Fiscal year ended September 30, 2022	–	0.00	–	0.00	0.00	–	–	–
Fiscal year ending September 30, 2023 (Forecast)	–	0.00	–	0.00	0.00		–	

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)	–	(177.50)

*** 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: Yes
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, 2022: 5,380,700 shares
As of September 30, 2021: 4,334,700 shares

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

As of September 30, 2022: 87 shares
As of September 30, 2021: 40 shares

3) Average number of shares during the period:

Fiscal year ended September 30, 2022: 4,855,940 shares
Fiscal year ended September 30, 2021: 4,153,592 shares

* These financial results are outside the scope of 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. These statements are not guarantees of future performance. Actual results may differ significantly from these forecasts due to various factors. Please refer to "1. Explanation of Financial Results (4) Outlook" on page 6 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. Explanation of 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 fiscal year under review.

In the Japanese pharmaceutical market, 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 fiscal year under review, at the five medical facilities where patients are being enrolled. In May 2022, the Company notified the PMDA of its intention to extend the trial period by 6 months because the target enrollment number had not been reached mainly due to the effects of protraction and resurgence of COVID-19, including fewer accidental injuries. As a result of this change, patient enrollment is expected to be completed in the second half of 2022 and the final follow-up for the last patient is expected to be completed in the first half of 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 fiscal year under review. Process validation of the drug product is currently being planned. The protracted 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 tests that were scheduled to be completed in the previous fiscal year were completed in the fiscal year under review.

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 to investigate possible combination with the transplantation technology for iPS cell-derived neural progenitor cells. 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, and in March 2022, Keio University and the Company jointly filed a patent application. 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) Amyotrophic lateral sclerosis (ALS)

A phase II clinical trial (placebo-controlled, double-blind trial) started in May 2016 at Tohoku University Hospital and Osaka University Hospital as an investigator-initiated trial 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. As the supplier of the investigational drug, the Company engaged 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 fiscal year under review.

In addition, during the same period, the Company has also 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 in March 2021 provided by Japan Agency for Medical Research and Development (AMED), a National Research and Development Agency.

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)

VFS is a condition in which vocal fold mucosa hardens and degenerates due to the formation of scar tissues (fibrosis). The investigator-initiated Phase I/II clinical trial confirmed the safety of intracordal administration of the recombinant human HGF and also detected signals of efficacy in some patients showing functional recovery of the vocal cord (J Tissue Eng Regen Med. 2018. 12:1031-1038.). 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.

In order to raise funds to finance clinical trial expenses, manufacture th 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).

(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 fiscal year under review, the Company supplied Claris with HGF drug substance required for manufacturing of investigational drugs. 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 development, the Company now receives a fixed annual technology access fee (royalty income). 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 fiscal year under review, the Company had business development discussion with potential business partners to expand development of acute SCI outside Japan.

In September 2021, “oremepermin alfa” was registered as the International Nonproprietary Name (INN) for recombinant human HGF protein (five amino acid-deleted, glycosylated; development code, KP-100), the main component of our development pipeline.

As a result of these efforts, business results for the fiscal year under review were as follows.

Net sales for the fiscal year under review amounted to ¥391,829 thousand (a year-on-year increase of 35.2%), while the

Company recorded an operating loss of ¥426,165 thousand (operating loss for the previous fiscal year was ¥357,880 thousand), ordinary loss of ¥330,339 thousand (ordinary loss for the previous fiscal year was ¥299,676 thousand) and loss of ¥331,829 thousand (loss for the previous fiscal year was ¥301,166 thousand).
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 September 30, 2022 increased by ¥573,057 thousand from the end of the previous fiscal year to ¥3,207,651 thousand (an increase of 21.8% from the end of the previous fiscal year). This was mainly due to an increase of ¥618,900 thousand in cash and deposits as a result of an increase in capital due to the exercise of share acquisition rights and a ¥34,780 thousand increase in inventories due to manufacturing and development. Non-current assets were mostly unchanged, increasing by ¥8 thousand from the end of the previous fiscal year to ¥1,040 thousand (an increase of 0.9% from the end of the previous fiscal year).
As a result, total assets increased by ¥573,066 thousand from the end of the previous fiscal year to ¥3,208,691 thousand (an increase of 21.7% from the end of the previous fiscal year).

Liabilities

Current liabilities as of September 30, 2022 increased by ¥35,627 thousand from the end of the previous fiscal year to ¥162,824 thousand (an increase of 28.0% from the end of the previous fiscal year). This was mainly due to an increase of ¥21,896 thousand in accounts payable-other and an increase of ¥12,711 thousand in advances received. Non-current liabilities increased ¥254,400 thousand, rising from ¥2,278 thousand at the end of the previous fiscal year to ¥256,679 thousand. This was mainly due to an increase of ¥254,374 thousand in long-term deposits received.
As a result, total liabilities increased by ¥290,028 thousand from the end of the previous fiscal year to ¥419,504 thousand (an increase of 224.0% from the end of the previous fiscal year).

Net assets

Net assets as of September 30, 2022 increased by ¥283,037 thousand from the end of the previous fiscal year to ¥2,789,187 thousand (an increase of 11.3% from the end of the previous fiscal year). This was mainly due to increases of ¥305,765 thousand in both share capital and legal capital surplus due to a capital increase as a result of the exercise of share acquisition rights, which offset the recording of a loss of ¥331,829 thousand.
The reduction of share capital and legal capital surplus in August 2022 decreased share capital and the legal capital surplus by ¥297,708 thousand and ¥3,458 thousand respectively, and the Company transferred these same amounts to other capital surplus and used this capital surplus of ¥301,166 thousand to offset the deficit in retained earnings brought forward.
This resulted in share capital of ¥59,877 thousand, capital surplus of ¥3,057,848 thousand, and negative retained earnings of ¥331,829 thousand.

(3) Explanation of Cash Flows

The balance of cash and cash equivalents (“cash”) at the end of the fiscal year under review increased ¥364,525 thousand from the end of the previous fiscal year to ¥2,502,046 thousand.
The status of cash flows in the fiscal year under review was as follows.

(Cash flows from operating activities)

Net cash provided by operating activities was ¥15,796 thousand (compared with net cash used of ¥560,922 thousand in the previous fiscal year). This mainly reflects proceeds from long-term deposits received of ¥254,374 thousand and subsidies received of ¥80,000 thousand, which offset a loss before income taxes of ¥330,339 thousand.

(Cash flows from investing activities)

Net cash used in investing activities was ¥254,383 thousand (there was no cash flow from investing activities during the previous fiscal year). This was mainly due to payments into time deposits of ¥254,374 thousand.

(Cash flows from financing activities)

Net cash provided by financing activities amounted to ¥603,112 thousand (compared with net cash provided of ¥595,904 thousand in the previous fiscal year). This was chiefly owing to proceeds from issuance of shares resulting from exercise of share acquisition rights of ¥602,073 thousand.

(4) Outlook

In net sales for the fiscal year ended September 30, 2022, the Company recorded sales from the supply of recombinant human HGF protein (KP-100) drug substance to Claris Biotherapeutics in the U.S. as well as a fixed technology access fee, which the Company receives annually starting from the first dose in the first clinical trial conducted by Claris Biotherapeutics. In the fiscal year ending September 30, 2023, the Company expects to receive only the technology access fee from Claris, without any sales for supply of the drug substance, and net sales are expected to amount to ¥68 million (a decrease of 82.4% year on year).

In selling, general and administrative expenses, the Company anticipates expenses for activities such as preparing for regulatory submission in anticipation of clinical trial completion for the acute SCI pipeline, clinical trial and related research activities for the VFS pipeline, new joint research projects with universities, and investigation of the acute SCI drug development in the Europe and the U.S., and the Company forecasts selling, general and administrative expenses of ¥1,062 million compared with ¥729 million in the fiscal year ended September 30, 2022 (an increase of 45.6% year on year).

As a result, operating loss for the fiscal year ending September 30, 2023 is projected to be ¥993 million (compared to an operating loss of ¥426 million in the fiscal year under review).

In non-operating income, the Company expects to receive subsidy income of ¥40 million for the acute SCI pipeline as it did in the fiscal year ended September 30, 2022, and the ordinary loss for the fiscal year ending September 30, 2023 will be ¥953 million (compared to an ordinary loss of ¥330 million in the fiscal year under review). There are no extraordinary income or losses projected as of the date of preparation of this forecast, and the loss for the fiscal year ending September 30, 2023 is expected to total ¥955 million (compared to a loss of ¥331 million in the fiscal year under review).

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.

3. Financial Statements and Principal Notes

(1) Balance Sheets

(Thousand yen)

	As of September 30, 2021	As of September 30, 2022
Assets		
Current assets		
Cash and deposits	2,137,520	2,756,420
Accounts receivable - trade	6,717	–
Merchandise and finished goods	88,413	–
Raw materials and supplies	226,681	349,875
Advance payments to suppliers	77,965	19,173
Prepaid expenses	12,856	11,751
Consumption taxes receivable	76,684	67,941
Other	7,754	2,487
Total current assets	2,634,594	3,207,651
Non-current assets		
Property, plant and equipment	–	–
Investments and other assets		
Guarantee deposits	1,031	1,040
Total investments and other assets	1,031	1,040
Total non-current assets	1,031	1,040
Total assets	2,635,625	3,208,691
Liabilities		
Current liabilities		
Accounts payable - other	30,968	52,864
Accrued expenses	3,049	2,959
Income taxes payable	1,490	1,490
Advances received	89,200	101,911
Deposits received	2,489	3,599
Total current liabilities	127,196	162,824
Non-current liabilities		
Asset retirement obligations	2,278	2,305
Long-term deposits received	–	254,374
Total non-current liabilities	2,278	256,679
Total liabilities	129,475	419,504
Net assets		
Shareholders' equity		
Share capital	51,820	59,877
Capital surplus		
Legal capital surplus	2,191,498	2,493,805
Other capital surplus	564,042	564,042
Total capital surplus	2,755,541	3,057,848
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(301,166)	(331,829)
Total retained earnings	(301,166)	(331,829)
Treasury shares	(45)	(75)
Total shareholders' equity	2,506,149	2,785,820
Share acquisition rights	–	3,366
Total net assets	2,506,149	2,789,187
Total liabilities and net assets	2,635,625	3,208,691

(2) Statements of Income

(Thousand yen)

	For the fiscal year ended September 30, 2021	For the fiscal year ended September 30, 2022
Net sales	289,756	391,829
Cost of sales		
Beginning finished goods inventory	–	88,413
Cost of products manufactured	160,011	–
Total	160,011	88,413
Ending finished goods inventory	88,413	–
Cost of finished goods sold	71,598	88,413
Gross profit	218,157	303,416
Selling, general and administrative expenses	576,038	729,581
Operating loss	(357,880)	(426,165)
Non-operating income		
Interest income	1	0
Subsidy income	82,236	80,000
Foreign exchange gains	–	21,923
Interest on tax refund	–	207
Other	56	2,082
Total non-operating income	82,293	104,213
Non-operating expenses		
Listing expenses	16,282	–
Share issuance costs	6,607	–
Share acquisition rights issuance costs	–	8,387
Foreign exchange losses	1,030	–
Other	168	–
Total non-operating expenses	24,090	8,387
Ordinary loss	(299,676)	(330,339)
Loss before income taxes	(299,676)	(330,339)
Income taxes - current	1,490	1,490
Total income taxes	1,490	1,490
Loss	(301,166)	(331,829)

(3) Statements of Changes in Net Assets

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

(Thousand yen)

	Shareholders' equity			
	Share capital	Capital surplus		
		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)
Loss				
Purchase of treasury shares				
Net changes in items other than shareholders' equity				
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				Share acquisition rights	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		–		–
Loss	(301,166)	(301,166)		(301,166)		(301,166)
Purchase of treasury shares			(45)	(45)		(45)
Net changes in items other than shareholders' equity					–	–
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

For the fiscal year ended September 30, 2022 (From October 1, 2021 to September 30, 2022)

(Thousand yen)

	Shareholders' equity			
	Share capital	Capital surplus		
		Legal capital surplus	Other capital surplus	Total capital surplus
Balance at beginning of period	51,820	2,191,498	564,042	2,755,541
Changes during period				
Issuance of new shares				
Issuance of new shares (Exercise of share acquisition rights)	305,765	305,765		305,765
Capital reduction	(297,708)	(3,458)	301,166	297,708
Deficit disposition			(301,166)	(301,166)
Loss				
Purchase of treasury shares				
Net changes in items other than shareholders' equity				
Total changes during period	8,057	302,307	–	302,307
Balance at end of period	59,877	2,493,805	564,042	3,057,848

	Shareholders' equity				Share acquisition rights	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	(301,166)	(301,166)	(45)	2,506,149	–	2,506,149
Changes during period						
Issuance of new shares				–		–
Issuance of new shares (Exercise of share acquisition rights)				611,531		611,531
Capital reduction				–		–
Deficit disposition	301,166	301,166		–		–
Loss	(331,829)	(331,829)		(331,829)		(331,829)
Purchase of treasury shares			(30)	(30)		(30)
Net changes in items other than shareholders' equity					3,366	3,366
Total changes during period	(30,663)	(30,663)	(30)	279,670	3,366	283,037
Balance at end of period	(331,829)	(331,829)	(75)	2,785,820	3,366	2,789,187

(4) Statements of Cash Flows

(Thousand yen)

	For the fiscal year ended September 30, 2021	For the fiscal year ended September 30, 2022
Cash flows from operating activities		
Loss before income taxes	(299,676)	(330,339)
Interest and dividend income	(1)	(0)
Share issuance costs	6,607	–
Listing expenses	16,282	–
Share acquisition rights issuance costs	–	8,387
Subsidy income	(82,236)	(80,000)
Decrease (increase) in trade receivables	99,093	6,717
Decrease (increase) in inventories	(268,727)	(34,780)
Decrease (increase) in accounts receivable - other	20	6,573
Decrease (increase) in advance payments to suppliers	(18,770)	58,792
Decrease (increase) in prepaid expenses	(8,813)	1,104
Increase (decrease) in accounts payable - other	(41,593)	21,896
Increase (decrease) in advances received	3,372	12,711
Other	(51,989)	4,095
Subtotal	(646,433)	(324,843)
Interest and dividends received	1	0
Subsidies received	87,000	80,000
Proceeds from long-term deposits received	–	254,374
Income taxes paid	(1,490)	(1,490)
Income taxes refund	–	7,754
Net cash provided by (used in) operating activities	(560,922)	15,796
Cash flow from investing activities		
Payments of leasehold and guarantee deposits	–	(8)
Payments into time deposits	–	(254,374)
Net cash provided by (used in) investing activities	–	(254,383)
Cash flows from financing activities		
Proceeds from issuance of shares	612,232	–
Payment of listing expenses	(16,282)	–
Purchase of treasury shares	(45)	(30)
Proceeds from issuance of share acquisition rights	–	1,070
Proceeds from issuance of shares resulting from exercise of share acquisition rights	–	602,073
Net cash provided by (used in) financing activities	595,904	603,112
Net increase (decrease) in cash and cash equivalents	34,981	364,525
Cash and cash equivalents at beginning of period	2,102,538	2,137,520
Cash and cash equivalents at end of period	2,137,520	2,502,046

(5) Notes to Financial Statements

Notes on Going Concern Assumption

Not applicable.

Changes in Accounting Policies

Application of Accounting Standard for Revenue Recognition, etc.

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

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

According to the transitional measures prescribed in Paragraph 89-3 of the Revenue Recognition Accounting Standard, information that breaks down revenue from contracts with customers for the previous fiscal year is not presented.

Application of Accounting Standard for Fair Value Measurement and Other Standards

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

Equity Method Earnings, Etc.

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	Fiscal Year Ended September 30, 2022
Lump-sum revenue from contracts	–
Milestone revenue	–
Revenue from research collaboration	–
Royalty income	56,183
Revenue from product sales	335,645
Revenue from contracts with customers	391,829
Other revenue	–
Revenues from external customers	391,829

Segment Information

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

Per Share Information

	Previous fiscal year (October 1, 2020 to September 30, 2021)	Fiscal year under review (October 1, 2021 to September 30, 2022)
Net assets per share	¥578.17	¥517.75
Net loss per share	(¥72.51)	(¥68.33)

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, 2021.

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

Item	Previous fiscal year (October 1, 2020 to September 30, 2021)	Fiscal year under review (October 1, 2021 to September 30, 2022)
Net loss per share		
Loss (thousand yen)	(301,166)	(331,829)
Amount not attributable to common shareholders (thousand yen)	–	–
Loss on common shares (thousand yen)	(301,166)	(331,829)
Average number of common shares during the period (shares)	4,153,592	4,855,940
Overview of potential shares not included in the calculation of diluted earnings per share due to lack of dilutive effect	–	–

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

Item	Previous fiscal year (As of September 30, 2021)	Fiscal year under review (As of September 30, 2022)
Total net assets (thousand yen)	2,506,149	2,789,187
Amount deducted from total net assets (thousand yen)	–	3,366
[Of which share acquisition rights (thousand yen)]	–	[3,366]
Net assets related to common shares at the end of the period (thousand yen)	2,506,149	2,785,820
Number of common shares at the end of the period used for the calculation of net assets per share (shares)	4,334,660	5,380,613

Significant Subsequent Events

Not applicable.