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Financial Results for the Fiscal Year Ended September 30, 2023 [Japanese GAAP] (Non-consolidated)

November 13, 2023

Company name: Kringle Pharma, Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4884
URL: https://www.kringle-pharma.com/en/
Representative: Kiichi Adachi, President & CEO
Contact: Koichi Murakami, Member of the Board, Director of Corporate Planning Management
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Scheduled date of the Annual General Meeting of Shareholders: December 22, 2023
Scheduled date of commencing dividend payments: —
Scheduled date of filing securities report: December 25, 2023
Availability of supplementary explanatory materials on financial results: Available
Schedule of financial results briefing session: Scheduled (for institutional investors, analysts, and individual investors)

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

1. Financial Results for the Fiscal Year Ended September 30, 2023 (October 1, 2022 - September 30, 2023)

(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, 2023	69	(82.3)	(888)	–	(852)	–	(854)	–
September 30, 2022	391	35.2	(426)	–	(330)	–	(331)	–

	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, 2023	(158.46)	–	(35.6)	(29.3)	–
September 30, 2022	(68.33)	–	(12.5)	(11.3)	(108.8)

Reference: Equity earnings (losses) of affiliates: Fiscal year ended September 30, 2023: ¥ — million
Fiscal year ended September 30, 2022: ¥ — 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, 2023	2,618	2,021	76.6	363.45
September 30, 2022	3,208	2,789	86.8	517.75

Reference: Equity: As of September 30, 2023: ¥2,007 million As of September 30, 2022: ¥2,785 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, 2023	(689)	(120)	69	1,761
September 30, 2022	15	(254)	603	2,502

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, 2022	–	0.00	–	0.00	0.00	–	–	–
Fiscal year ended September 30, 2023	–	0.00	–	0.00	0.00	–	–	–
Fiscal year ending September 30, 2024 (Forecast)	–	0.00	–	0.00	0.00		–	

3. Financial Results Forecast for the Fiscal Year Ending September 30, 2024 (October 1, 2023 - September 30, 2024)

(% 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	272	292.8	(1,133)	–	(1,107)	–	(1,109)	–	(200.86)

*** 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, 2023: 5,522,200 shares
As of September 30, 2022: 5,380,700 shares

2) Total number of treasury shares at the end of the period:
As of September 30, 2023: 87 shares
As of September 30, 2022: 87 shares

3) Average number of shares during the period:
Fiscal year ended September 30, 2023: 5,390,205 shares
Fiscal year ended September 30, 2022: 4,855,940 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.

Amidst the above business environment, the Company continued to focus its managerial resources on the recombinant human hepatocyte growth factor (HGF) protein and developed the business activities outlined below, in the belief that development of recombinant human HGF protein (development code: KP-100) will lead to therapeutic innovation, creating business opportunities and maximizing the value of the Company.

1. Drug development activities

(a) Acute spinal cord injury (SCI)

The Company conducted a Phase I/II clinical trial with Professor Masaya Nakamura of the Department of Orthopaedic Surgery, Keio University School of Medicine as a coordinating investigator and obtained results that confirmed the safety and indicated the efficacy of the drug. The Company designed the Phase III clinical trial to verify the proof of concept (POC; a preliminary evidence of efficacy detected in humans with a new drug candidate under development) obtained in the Phase I/II clinical trial. On June 9, 2020, the Company submitted a clinical trial notification for the Phase III study to the Pharmaceuticals and Medical Devices Agency (PMDA).

In July 2020, the Company started the Phase III study at Spinal Injuries Center, Hokkaido Spinal Cord Injury Center, and Murayama Medical Center. With the addition of Japanese Red Cross Kobe Hospital and Aijinkai Rehabilitation Hospital in March 2021, a total of five medical facilities conducted the Phase III clinical trial, and the enrollment of the last patients was completed in April 2023*.

* The final follow-up for the last patient was completed in October 2, 2023.

In the meantime, the Company had a preliminary consultation with the U.S. Food and Drug Agency (FDA) in September 2023 in preparation for clinical development in the U.S.

In order to submit marketing authorization application for the treatment of acute SCI, the Company is also conducting various tests related to the process of manufacturing recombinant human HGF. Trial manufacturing (process validation) of the drug substance using the same process as commercial manufacturing, as required for the submission, was completed in the previous fiscal year. Process validation for manufacturing of the drug product was also completed this fiscal year.

For the purpose of identifying more effective administration methods and timing with recombinant human HGF for SCI, the Company launched a joint research program with Keio University School of Medicine in February 2021. In this joint research program, the transplantation of human induced iPS cell-derived neural stem/progenitor cells (hiPSC-NS/PC) owned by Keio University, combined with the scaffold-mediated delivery of HGF developed by the Company, demonstrated improvement in recovery of motor function in animal model of chronic complete spinal cord

injury. In March 2022, Keio University and the Company jointly filed a patent application, followed by the filing of an application claiming priority based on the said patent application in March 2023. Furthermore, confirming 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, Keio University and the Company jointly filed a second patent application in September 2022, and a priority claim based on this patent application in September 2023. 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 U.S., Japan, Canada and Korea, and adding Europe further created a favorable intellectual property environment for the Company to develop HGF drug business worldwide.

(b) Vocal fold scarring (VFS)

For VFS, a disorder in which the vocal fold mucosa hardens and degenerates (fibrosis), an investigator-initiated Phase I/II clinical trial confirmed the safety of intracordal administration of the recombinant human HGF. It also detected signals of efficacy showing functional recovery of the vocal cord with some patients (J Tissue Eng Regen Med. 2017; 1-8.). Following a preliminary consultation with PMDA in July 2019 and subsequent discussions with Kyoto Prefectural University of Medicine, the Company submitted a clinical trial application for a Phase III study (placebo-controlled, double-blind trial) in October 2022 which was then accepted by PMDA. The Company then began a clinical trial at University Hospital, Kyoto Prefectural University of Medicine, and the first subject was enrolled in January 2023. In May 2023, Kurume University Hospital, Tohoku University Hospital, Kawasaki Medical School Hospital and Nihon University Hospital were newly added as medical institutions for carrying out clinical trials, and case registration is currently moving forward at a total of five facilities.

In order to raise funds to finance clinical trial expenses, manufacture the investigational drugs, and develop a commercial formulation, the Company issued share acquisition rights in November 2021. By July 2022, all of these rights had been exercised. In addition, the Company has been utilizing public funds since April 2022, with its VFS development being selected for the Cyclic Innovation for Clinical Empowerment (CiCLE) project operated by the Japan Agency for Medical Research and Development (AMED).

(c) Amyotrophic lateral sclerosis (ALS)

A phase II clinical trial (placebo-controlled, double-blind trial) was conducted at Tohoku University Hospital and Osaka University Hospital as an investigator-initiated trial that started in May 2016, led by Professor Masashi Aoki of the Department of Neurology, Tohoku University. In November 2020, the enrollment of patients was completed, and the final follow-up for the last patient was completed in December 2021. Subsequent data analysis at Tohoku University has shown no statistically significant differences between the active and placebo groups for the primary and secondary endpoints. On the other hand, there were cases in which progression was slow in the active drug group, suggesting that more detailed analysis is required to interpret the results of this study. Regarding safety, the incidence of adverse events was similar between the active drug group and the placebo group, confirming tolerability. Going forward, the Company plans to implement additional analysis including biomarker evaluation in cooperation with Tohoku University.

(d) Supply of drug substance to Claris Biotherapeutics, Inc.

The Company concluded a license and supply agreement with Claris Biotherapeutics, Inc. of the U.S. in April 2020

to supply HGF drug substance for clinical development by Claris to treat ophthalmologic diseases in the U.S.
During the previous fiscal year, the Company supplied Claris with HGF drug substance required for manufacturing of investigational drugs, but there was no supply of HGF drug substance during the fiscal year under review. Claris filed an investigational new drug (IND) application* in May 2021 to initiate a Phase I/II clinical trial for neurotrophic keratitis utilizing the various preclinical and clinical information related to HGF provided by the Company, and the first patient received treatment in August 2021. With this developmental milestone, the Company now receives a fixed annual technology access fee (royalty income), and recorded the fee for the applicable period in net sales. To initiate the clinical trial in Canada as well, Claris filed a clinical trial application to Health Canada in July 2022, which was approved. As now the trial continues in both the U.S. and Canada, further acceleration of patient enrolment is expected.
Furthermore, the Company formed a business alliance with Claris in September 2023 to improve the efficiency of the manufacturing method for recombinant human HGF. The purpose of the alliance is to meet growing global demand in the future and to achieve stable worldwide supply of recombinant human HGF.
* 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 by seeking new research proposals from researchers regarding the use of recombinant human HGF.
Moreover, in September 2023, the Company issued share acquisition rights, and decided to use part of the funds raised for the creation of a new pipeline including the implementation and expansion of joint non-clinical research.

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 addition, the Company issued share acquisition rights in September 2023, for the purpose of partially funding clinical development and manufacturing development (improvement of the efficiency of the manufacturing method for recombinant human HGF) for acute SCI in the U.S. With this move it expected to clarify the Company's development strategy in the U.S., the largest pharmaceutical market in the world, and accelerate business alliance discussions.
In September 2021, "oremepermin alfa" was registered as the International Nonproprietary Name (INN) for recombinant human HGF (five amino acid-deleted, glycosylated; development code, KP-100), the drug substance 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 ¥69,250 thousand (a year-on-year decrease of 82.3%), reflecting the absence of supply of drug substance. The Company recorded an operating loss of ¥888,762 thousand (operating loss for the previous fiscal year was ¥426,165 thousand), ordinary loss of ¥852,660 thousand (ordinary loss for the previous fiscal year was ¥330,339 thousand) and loss of ¥854,151 thousand (loss for the previous fiscal year was ¥331,829 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, 2023 decreased by ¥590,033 thousand from the end of the previous fiscal year to ¥2,617,617 thousand (a decrease of 18.4% from the end of the previous fiscal year). This was mainly due to a decrease of ¥619,930 thousand in cash and deposits as a result of the payment of R&D expenses including VFS clinical trial expenses. Non-current assets were ¥1,040 thousand, unchanged from the end of the previous fiscal year.

As a result, total assets decreased by ¥590,033 thousand from the end of the previous fiscal year to ¥2,618,657 thousand (a decrease of 18.4% from the end of the previous fiscal year).

Liabilities

Current liabilities as of September 30, 2023 increased by ¥46,229 thousand from the end of the previous fiscal year to ¥209,054 thousand (an increase of 28.4% from the end of the previous fiscal year). This was mainly due to an increase of ¥118,797 thousand in accounts payable-other, which was partially offset by a decrease of ¥75,911 thousand in advances received. Non-current liabilities increased by ¥131,220 thousand from the end of the previous fiscal year to ¥387,900 thousand (an increase of 51.1% from the end of the previous fiscal year). This primarily reflected an increase of ¥120,875 thousand in long-term deposits received.

As a result, total liabilities increased by ¥177,450 thousand from the end of the previous fiscal year to ¥596,955 thousand (an increase of 42.3% from the end of the previous fiscal year).

Net assets

Net assets as of September 30, 2023 decreased by ¥767,484 thousand from the end of the previous fiscal year to ¥2,021,702 thousand (a decrease of 27.5% from the end of the previous fiscal year). This primarily reflected the recording of a net loss of ¥854,151 thousand, which was partially offset by increases of both share capital and legal capital surplus of ¥37,668 thousand each as a result of capital increase by way of execution of share acquisition rights. This resulted in share capital of ¥97,546 thousand, capital surplus of ¥3,095,517 thousand, and negative retained earnings of ¥1,185,981 thousand.

(3) Explanation of Cash Flows

The balance of cash and cash equivalents (“cash”) at the end of the fiscal year under review decreased ¥740,806 thousand from the end of the previous fiscal year to ¥1,761,239 thousand.

The status of cash flows in the fiscal year under review was as follows.

(Cash flows from operating activities)

Net cash used in operating activities was ¥689,095 thousand (compared with net cash provided of ¥15,796 thousand in the previous fiscal year). This was mainly due to a loss before income taxes of ¥852,660 thousand, offsetting an increase in cash resulting from a rise in accounts payable -other of ¥118,797 thousand.

(Cash flows from investing activities)

Net cash used in investing activities was ¥120,875 thousand (net cash used in investing activities during the previous fiscal year was ¥254,383 thousand). This was due to ¥120,875 thousand of payments into time deposits.

(Cash flows from financing activities)

Net cash provided by financing activities amounted to ¥69,164 thousand (compared with net cash provided of ¥603,112 thousand in the previous fiscal year). This was chiefly owing to proceeds from issuance of shares resulting from exercise of share acquisition rights of ¥67,922 thousand.

(4) Outlook

In net sales for the fiscal year ended September 30, 2023, the Company recorded ¥69 million, only 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 U.S. In the fiscal year ending September 30, 2024, the Company expects to receive a milestone payment from Maruishi Pharmaceutical Co., Ltd. relating to approval to manufacture and market an acute SCI pipeline drug in Japan, in addition to the technology access fee from Claris, and net sales are expected to amount to ¥272 million (an increase of 292.8% year on year).

In selling, general and administrative expenses, the Company anticipates expenses for regulatory submission activities for the acute SCI pipeline, clinical trial activities for the VFS pipeline, additional analysis activities and related research activities in the ALS pipeline, new joint research projects with universities, and investigation activities for acute SCI drug development in the U.S., and the Company forecasts selling, general and administrative expenses of ¥1,342 million in the fiscal year ending September 30, 2024 compared with ¥958 million in the fiscal year ended September 30, 2023 (an increase of 40.1% year on year).

As a result, operating loss for the fiscal year ending September 30, 2024 is projected to be ¥1,133 million (compared to an operating loss of ¥888 million in the fiscal year under review).

In non-operating income, the Company expects to receive subsidy income of ¥26 million for the acute SCI pipeline as it did in the fiscal year ended September 30, 2023, and the ordinary loss for the fiscal year ending September 30, 2024 will be ¥1,107 million (compared to an ordinary loss of ¥852 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, 2024 is expected to total ¥1,109 million (compared to a loss of ¥854 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, 2022	As of September 30, 2023
Assets		
Current assets		
Cash and deposits	2,756,420	2,136,490
Accounts receivable - trade	–	7,560
Raw materials and supplies	349,875	364,056
Advance payments to suppliers	19,173	21,065
Prepaid expenses	11,751	14,002
Consumption taxes receivable	67,941	74,290
Other	2,487	151
Total current assets	3,207,651	2,617,617
Non-current assets		
Property, plant and equipment	–	–
Investments and other assets		
Guarantee deposits	1,040	1,040
Total investments and other assets	1,040	1,040
Total non-current assets	1,040	1,040
Total assets	3,208,691	2,618,657
Liabilities		
Current liabilities		
Accounts payable - other	52,864	171,662
Accrued expenses	2,959	5,206
Income taxes payable	1,490	1,490
Advances received	101,911	26,000
Deposits received	3,599	4,694
Total current liabilities	162,824	209,054
Non-current liabilities		
Asset retirement obligations	2,305	2,305
Long-term accounts payable - other	–	10,345
Long-term deposits received	254,374	375,250
Total non-current liabilities	256,679	387,900
Total liabilities	419,504	596,955
Net assets		
Shareholders' equity		
Share capital	59,877	97,546
Capital surplus		
Legal capital surplus	2,493,805	2,531,474
Other capital surplus	564,042	564,042
Total capital surplus	3,057,848	3,095,517
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(331,829)	(1,185,981)
Total retained earnings	(331,829)	(1,185,981)
Treasury shares	(75)	(75)
Total shareholders' equity	2,785,820	2,007,006
Share acquisition rights	3,366	14,696
Total net assets	2,789,187	2,021,702
Total liabilities and net assets	3,208,691	2,618,657

(2) Statements of Income

(Thousand yen)

	For the fiscal year ended September 30, 2022	For the fiscal year ended September 30, 2023
Net sales	391,829	69,250
Cost of sales		
Beginning finished goods inventory	88,413	–
Cost of products manufactured	–	–
Total	88,413	–
Ending finished goods inventory	–	–
Cost of finished goods sold	88,413	–
Gross profit	303,416	69,250
Selling, general and administrative expenses	729,581	958,012
Operating loss	(426,165)	(888,762)
Non-operating income		
Interest income	0	5
Subsidy income	80,000	43,048
Foreign exchange gains	21,923	294
Interest on tax refund	207	83
Other	2,082	0
Total non-operating income	104,213	43,431
Non-operating expenses		
Share acquisition rights issuance costs	8,387	7,330
Total non-operating expenses	8,387	7,330
Ordinary loss	(330,339)	(852,660)
Loss before income taxes	(330,339)	(852,660)
Income taxes - current	1,490	1,490
Total income taxes	1,490	1,490
Loss	(331,829)	(854,151)

(3) Statements of Changes in Net Assets

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 (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 (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

For the fiscal year ended September 30, 2023 (From October 1, 2022 to September 30, 2023)

(Thousand yen)

	Shareholders' equity			
	Share capital	Capital surplus		
		Legal capital surplus	Other capital surplus	Total capital surplus
Balance at beginning of period	59,877	2,493,805	564,042	3,057,848
Changes during period				
Issuance of new shares (Exercise of share acquisition rights)	37,668	37,668		37,668
Capital reduction				
Deficit disposition				
Loss				
Purchase of treasury shares				
Net changes in items other than shareholders' equity				
Total changes during period	37,668	37,668	–	37,668
Balance at end of period	97,546	2,531,474	564,042	3,095,517

	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	(331,829)	(331,829)	(75)	2,785,820	3,366	2,789,187
Changes during period						
Issuance of new shares (Exercise of share acquisition rights)				75,337		75,337
Capital reduction				–		–
Deficit disposition				–		–
Loss	(854,151)	(854,151)		(854,151)		(854,151)
Purchase of treasury shares				–		–
Net changes in items other than shareholders' equity					11,329	11,329
Total changes during period	(854,151)	(854,151)	–	(778,814)	11,329	(767,484)
Balance at end of period	(1,185,981)	(1,185,981)	(75)	2,007,006	14,696	2,021,702

(4) Statements of Cash Flows

(Thousand yen)

	For the fiscal year ended September 30, 2022	For the fiscal year ended September 30, 2023
Cash flows from operating activities		
Loss before income taxes	(330,339)	(852,660)
Interest and dividend income	(0)	(5)
Share acquisition rights issuance costs	8,387	7,330
Subsidy income	(80,000)	(43,048)
Decrease (increase) in trade receivables	6,717	(7,560)
Decrease (increase) in inventories	(34,780)	(14,180)
Decrease (increase) in accounts receivable - other	6,573	(4,179)
Decrease (increase) in advance payments to suppliers	58,792	(1,891)
Decrease (increase) in prepaid expenses	1,104	(2,250)
Increase (decrease) in accounts payable - other	21,896	118,797
Increase (decrease) in advances received	12,711	(61,911)
Increase (decrease) in long-term accounts payable - other	–	10,345
Other	4,095	13,680
Subtotal	(324,843)	(837,533)
Interest and dividends received	0	5
Subsidies received	80,000	29,048
Proceeds from long-term deposits received	254,374	120,875
Income taxes paid	(1,490)	(1,490)
Income taxes refund	7,754	–
Net cash provided by (used in) operating activities	15,796	(689,095)
Cash flow from investing activities		
Payments of leasehold and guarantee deposits	(8)	–
Payments into time deposits	(254,374)	(120,875)
Net cash provided by (used in) investing activities	(254,383)	(120,875)
Cash flows from financing activities		
Purchase of treasury shares	(30)	–
Proceeds from issuance of share acquisition rights	1,070	1,242
Proceeds from issuance of shares resulting from exercise of share acquisition rights	602,073	67,922
Net cash provided by (used in) financing activities	603,112	69,164
Net increase (decrease) in cash and cash equivalents	364,525	(740,806)
Cash and cash equivalents at beginning of period	2,137,520	2,502,046
Cash and cash equivalents at end of period	2,502,046	1,761,239

(5) Notes to Financial Statements

Notes on going concern assumption

Not applicable.

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	Fiscal year ended September 30, 2023
Lump-sum revenue from contracts	–	–
Milestone revenue	–	–
Royalty income	56,183	69,250
Revenue from product sales	335,645	–
Revenue from contracts with customers	391,829	69,250
Other revenue	–	–
Revenues from external customers	391,829	69,250

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, 2021 to September 30, 2022)	Fiscal year under review (October 1, 2022 to September 30, 2023)
Net assets per share	¥517.75	¥363.45
Net loss per share	(¥68.33)	(¥158.46)

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

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

Item	Previous fiscal year (October 1, 2021 to September 30, 2022)	Fiscal year under review (October 1, 2022 to September 30, 2023)
Net loss per share		
Loss (thousand yen)	(331,829)	(854,151)
Amount not attributable to common shareholders (thousand yen)	–	–
Loss on common shares (thousand yen)	(331,829)	(854,151)
Average number of common shares during the period (shares)	4,855,940	5,390,205
Overview of potential shares not included in the calculation of diluted earnings per share due to lack of dilutive effect	–	–

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

Item	Previous fiscal year (As of September 30, 2022)	Fiscal year under review (As of September 30, 2023)
Total net assets (thousand yen)	2,789,187	2,021,702
Amount deducted from total net assets (thousand yen)	3,366	14,696
(Of which share acquisition rights (thousand yen))	[3,366]	[14,696]
Net assets related to common shares at the end of the period (thousand yen)	2,785,820	2,007,006
Number of common shares at the end of the period used for the calculation of net assets per share (shares)	5,380,613	5,522,113

Significant subsequent events

Exercise of share acquisition rights

During the period between October 1, 2023 and November 13, 2023, the 13th series of share acquisition rights were exercised. An overview of the exercise of these share acquisition rights is shown below.

1. Number of share acquisition rights exercised 2,190
2. Type and number of shares issued 219,000 common shares
3. Increase in share capital ¥69,569 thousand
4. Increase in legal capital surplus ¥69,569 thousand