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November 14, 2024

Consolidated Financial Results for the Nine Months Ended September 30, 2024 (under IFRS)

Company name: Kubota Pharmaceutical Holdings Co., Ltd.
 Listing: Tokyo Stock Exchange
 Securities code: 4596
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 Scheduled date to commence dividend payments: –
 Preparation of supplementary material on financial results: Yes
 Holding of financial results presentation meeting: None

(Yen amounts are rounded to the nearest million, unless otherwise noted.)

1. Consolidated financial results for the nine months ended September 30, 2024 (January 1, 2024 to September 30, 2024)

(1) Consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Revenue		Operating profit (loss)		Profit (loss) before tax		Net profit (loss)		Profit (loss) attributable to owners of parent		Total comprehensive income (loss)	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Nine months ended September 30, 2024	17	(43.9)	(955)	–	(1,000)	–	(1,000)	–	(1,000)	–	(997)	–
Nine months ended September 30, 2023	31	965.5	(1,031)	–	(1,027)	–	(1,027)	–	(1,027)	–	(992)	–

	Basic earnings (loss) per share	Diluted earnings (loss) per share
	Yen	Yen
Nine months ended September 30, 2024	(17.76)	(17.76)
Nine months ended September 30, 2023	(18.53)	(18.53)

(2) Consolidated financial position

	Total assets	Total shareholders' equity (deficit)	Equity attributable to owners of parent	Ratio of equity attributable to owners of parent
As of	Millions of yen	Millions of yen	Millions of yen	%
September 30, 2024	1,923	1,696	1,696	88.2
December 31, 2023	3,017	2,647	2,647	87.7

2. Cash dividends

	Annual dividends per share				
	First quarter-end	Second quarter-end	Third quarter-end	Fiscal year-end	Total
Fiscal year ended December 31, 2023	Yen –	Yen 0.00	Yen –	Yen 0.00	Yen 0.00
Fiscal year ending December 31, 2024	–	0.00	–		
Fiscal year ending December 31, 2024 (Forecast)				0.00	0.00

(Note) Revisions to the forecast of cash dividends most recently announced: None

3. Consolidated earnings forecasts for the fiscal year ending December 31, 2024 (January 1, 2024 to December 31, 2024)

The earnings forecasts for the fiscal year ending December 31, 2024, are not shown because they cannot be reasonably calculated at this time. Please refer to “1. Overview of Operating Results and Others, (4) Explanation of consolidated earnings forecasts and other forward-looking statements” on page 5 of the attached materials for details concerning the reasons.

*** Notes**

(1) Significant changes in scope of consolidation during the period: None

Newly included: None

Excluded: None

(2) Changes in accounting policies and changes in accounting estimates

(i) Changes in accounting policies required by IFRS: None

(ii) Changes in accounting policies due to other reasons: None

(iii) Changes in accounting estimates: None

(3) Number of issued shares (ordinary shares)

(i) Total number of issued shares at end of the period (including treasury shares)

As of September 30, 2024	56,427,988 shares
As of December 31, 2023	56,062,988 shares

(ii) Number of treasury shares at end of the period

As of September 30, 2024	71 shares
As of December 31, 2023	71 shares

(iii) Average number of shares outstanding during the period (cumulative from the beginning of the fiscal year)

For the nine months ended September 30, 2024	56,280,458 shares
For the nine months ended September 30, 2023	55,435,721 shares

* Review of the Japanese-language originals of the attached quarterly consolidated financial statements by certified public accountants or an audit corporation: None

* Proper use of earnings forecasts, and other special items

The earnings forecasts and other forward-looking statements contained in these materials are based on information currently available to Kubota Pharmaceutical Holdings Co., Ltd. (the "Company") and on certain assumptions deemed to be reasonable by the Company. Actual business performance and other results may differ substantially due to various factors. Please refer to "1. Overview of Operating Results and Others, (4) Explanation of consolidated earnings forecasts and other forward-looking statements" on page 5 of the attached materials for matters relating to earnings forecasts.

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1. Overview of Operating Results and Others

(1) Overview of operating results for the period under review

The Kubota Pharmaceutical Group (the “Group”) is an ophthalmic medical solutions company specializing in the field of ophthalmology that conducts research and development of drugs and medical devices globally.

During the nine months ended September 30, 2024, the outlook for the global economy has remained uncertain given factors such as soaring costs of raw materials and transport due to energy concerns owing to the prolongation of the situations in Israel and Ukraine as well as rapid exchange rate fluctuations.

In this market environment, the Group proceeded with research and development as follows.

Medical devices

Wearable myopia control device (Kubota Glass)

Currently under development by the Group, Kubota Glass technology is the Group’s original active stimulation technology that aims to slow the progression of myopia and treat it by using artificial light to stimulate the retina. In 2020, the Company’s US subsidiary, Kubota Vision Inc. (“KV”), conducted a clinical study of 12 subjects with a prototype desktop device that used Kubota Glass technology to verify the impact on the axial length of the eye. The study demonstrated that axial length in the tested eye decreased compared to the control eye. Next, KV completed verification that a similar effect was demonstrated with a wearable device using the same technology in 25 subjects aged 18 to 35 with myopia. In another clinical study, the 25 adult patients had their retinas stimulated by light (myopic defocus) for 1.5 hours a day, 3-5 times a week for 4 months with a desktop device using Kubota Glass technology and showed an average of 101% inhibition of spherical equivalence myopia progression and 38% reduction in the axial length elongation on an annualized basis when compared to the control eye. Usually, the axial length increases or stops growing with age. The shortening of the axial length due to artificial light compared to the control eye is a world first. The Group envisions applications of this technology in smart glasses and smart contact lenses for a world without eyeglasses. In 2021, the Group received medical device registration approval in Taiwan and received “ISO 13485:2016” certification for the design and development of ophthalmic medical devices. In 2022, the Group completed the registration of medical devices with the U.S. FDA and began sales at some ophthalmic clinics in the U.S. and Japan as a soft launch and also opened its first direct retail location, Kubota Glass Store, in Tokyo in December 2022. The Group is proceeding with initiatives for sales expansion while continuing clinical studies aimed at obtaining more evidence and other activities. The Group’s policy going forward is to proactively collaborate with other companies on global expansion, in addition to strengthening marketing activities in Japan, which will lead to business growth. At the same, we are progressing the review of our manufacturing processes, and building an operational framework that will enable greater cost-competitiveness and quicker product delivery.

Home-based and remote medical monitoring device

The Group is developing the Patient Based Ophthalmology Suite (PBOS) for a compact optical coherence tomography (OCT) device. It is a compact version of an OCT, which is used to test the condition of the retina in ophthalmology. This home-based ophthalmology device solution anticipates growing demand in the home-based and remote medical care field, including mobile health. It is a testing device that enables patients diagnosed and treated for wet age-related macular degeneration (AMD) and diabetic macular edema (DME) to measure the state of their retina themselves at home. By establishing a system that enables physicians to remotely examine the progression of symptoms such as changes in retinal anatomy and vision via the internet, the Group aims to help individual patients receive optimal ophthalmological treatment to maintain and improve their vision prior to requiring an office visit. Since January 2023, the Group has conducted evaluations regarding the possibility of this model being put to practical use as a screening device for diabetic retinopathy patients and a clinical study that compared this model with OCT devices on the market at Joslin Diabetes Center, which is affiliated with Harvard Medical School. In Japan, a specific clinical trial at Shinshu University Hospital (announced on May 7, 2024) has advanced to the next phase of testing, which will explore the potential of the technology for effectively monitoring patients in their own homes. The Group has been exploring

the possibility of joint development and commercialization with partner companies while verifying the ideal working model.

Small molecule compounds

With regard to emixustat hydrochloride (“emixustat”), the Group completed the enrollment of the first subject of the phase 3 clinical study for Stargardt disease in November 2018, finally completing the enrollment of 194 subjects, and concluded this phase 3 clinical study. For the results of the aggregation and analysis of the database for the clinical study, the primary endpoint and secondary endpoints were not achieved, and there were no significant differences between the treatment groups. The rate of macular atrophy progression, which was the primary endpoint, was 1.280 mm²/year for the group receiving emixustat and 1.309 mm²/year for the group receiving the placebo (p=0.8091). However, the tolerability of emixustat was good, and the safety profile was consistent with that observed in prior research.

As a result of further subsequent analysis, when comparing the subject group with a smaller atrophic lesion area at the baseline time against the group that received the placebo, it was demonstrated that the progression of the atrophic lesion was significantly slowed in the group receiving emixustat, and a subgroup analysis was conducted to verify this. A multi-factor analysis was performed on the subgroup of subjects with smaller lesions at baseline, controlling for the baseline factors identified in univariate and multi-factor analyses to affect lesion progression in this subgroup. The result of this analysis found that the progression rate of macular atrophy in the group receiving emixustat was slowed by 40.8% at Month 24 compared with the placebo group (p=0.0206, emixustat receiving group n=34, placebo group n=21). Given the above result, the Group plans to continue its activities, such as searching for co-development partners, while reconsidering its future plans for emixustat.

For the nine months ended September 30, 2024, revenue was ¥17 million, a decrease of 43.9% year on year, and cost of sales was ¥4 million, a decrease of 59.2% year on year. Research and development expenses, selling, general and administrative expenses are as follows:

Research and development expenses

Research and development expenses for the nine months ended September 30, 2024, was ¥419 million, a decrease of ¥165 million, or 28.2%, year on year. This was mainly due to decreases in research and development expenses for emixustat and the wearable myopia control device.

(Unit: Thousands of yen or %)

	Nine months ended September 30, 2023	Nine months ended September 30, 2024	Increase (Decrease)	Change (%)
Research and development expenses	583,655	419,037	(164,618)	(28.2)

Selling, general and administrative expenses

Selling, general and administrative expenses for the nine months ended September 30, 2024, was ¥549 million, an increase of ¥82 million, or 17.4%, year on year. This was mainly due to increases in paid compensation, among other items, associated with Kubota Glass, despite a decrease in patent-related expenses year on year.

(Unit: Thousands of yen or %)

	Nine months ended September 30, 2023	Nine months ended September 30, 2024	Increase (Decrease)	Change (%)
Selling, general and administrative expenses	467,876	549,433	81,557	17.4

(2) Overview of financial position as of September 30, 2024

Current assets

Current assets as of the end of the third quarter of the current fiscal year was ¥1,867 million, a decrease of ¥1,003 million from the end of the previous fiscal year. This was mainly due to a decrease in cash and cash equivalents.

Non-current assets

Non-current assets as of the end of the third quarter of the current fiscal year was ¥57 million, a decrease of ¥90 million from the end of the previous fiscal year. This was mainly due to a decrease in property, plant and equipment.

Current liabilities

Current liabilities as of the end of the third quarter of the current fiscal year was ¥224 million, a decrease of ¥59 million from the end of the previous fiscal year. This was mainly due to decreases in trade payables and accrued liabilities.

Non-current liabilities

Non-current liabilities as of the end of the third quarter of the current fiscal year was ¥4 million, a decrease of ¥83 million from the end of the previous fiscal year. This was due to a decrease in lease liabilities.

Shareholders' equity (Accumulated deficit)

Shareholders' equity as of the end of the third quarter of the current fiscal year was ¥1,696 million, a decrease of ¥951 million from the end of the previous fiscal year. This was mainly due to an increase in loss brought forward (accumulated deficit) due to the recording of net loss.

(3) Overview of cash flows for the nine months ended September 30, 2024

Cash and cash equivalents include all highly liquid short-term investments with a maturity of three months or less from the date of acquisition, and cash equivalents consist of money market funds. Investments with a maturity of three months to one year as of the date of acquisition are classified as short-term investments.

The cash, cash equivalents and short- and long-term financial instruments held by the Group were ¥3,131 million as of September 30, 2023, and ¥1,740 million as of September 30, 2024. Deposits at third-party financial institutions may exceed the applicable insurance limits of the Federal Deposit Insurance Corporation and Securities Investor Protection Corporation.

Cash flows from operating activities

Cash and cash equivalents ("cash") used in operating activities was ¥1,048 million for the nine months ended September 30, 2023, and ¥951 million for the nine months ended September 30, 2024. The decrease of ¥97 million in net cash used, was mainly due to a year-on-year decrease in cash related to the payment of research and development expenses and general and administrative expenses for the nine months ended September 30, 2024.

Cash flows from investing activities

Net cash used in investing activities was ¥21 million for the nine months ended September 30, 2023 and ¥29 million for the nine months ended September 30, 2024. The increase of ¥8 million in net cash provided was mainly due to an increase in purchase of property, plant and equipment.

Cash flows from financing activities

Net cash provided by investing activities was ¥111 million for the nine months ended September 30, 2023, and net cash used in investing activities was ¥49 million for the nine months ended September

30, 2024. The decrease in net cash provided was mainly due to a year-on-year decrease in proceeds from issuance of ordinary shares upon exercise of share acquisition rights for the nine months ended September 30, 2024.

(4) Explanation of consolidated earnings forecasts and other forward-looking statements

Revenue from sales of Kubota Glass accounts for almost all of the current revenue of the Company. With regard to expenditures, while reflecting customer opinions, etc. in the current version of the product and continuing efforts to reduce manufacturing expenses, the Group has established the priority for additional development. As a result, development expenses may fluctuate significantly. In addition, with regard to revenue, as Kubota Glass is an extremely novel product, it is difficult to determine the objective demand at this time.

Based on the above, the Group has decided to postpone the disclosure of the earnings forecasts for the full year because the consolidated earnings forecasts for the fiscal year ending December 31, 2024, are still difficult to objectively calculate at this time. They will be promptly disclosed as soon as it becomes possible to make a reasonable calculation in light of future business conditions.

2. Condensed Quarterly Consolidated Financial Statements and Significant Notes Thereto

(1) Condensed quarterly consolidated statements of financial position

	As of December 31, 2023	(Thousands of yen) As of September 30, 2024
Assets		
Current assets		
Cash and cash equivalents	2,767,639	1,740,111
Trade receivables	1,964	1,166
Inventories	36,849	60,463
Other current assets	62,989	64,782
Total current assets	2,869,441	1,866,522
Non-current assets		
Property, plant and equipment	129,457	55,435
Other non-current assets	17,942	1,499
Total non-current assets	147,399	56,934
Total assets	3,016,840	1,923,456
Liabilities and equity		
Liabilities		
Current liabilities		
Trade payables	34,547	13,977
Accrued liabilities	110,085	77,321
Accrued compensation	72,276	62,362
Lease liabilities	55,659	60,511
Other current liabilities	10,347	9,888
Total current liabilities	282,914	224,059
Non-current liabilities		
Lease liabilities	87,194	3,777
Total non-current liabilities	87,194	3,777
Total liabilities	370,108	227,836
Shareholders' equity		
Share capital	2,141,113	24,594
Capital surplus	27,638,335	27,854,102
Accumulated deficit	(25,670,256)	(24,723,478)
Other components of equity	(1,462,460)	(1,459,598)
Total equity attributable to owners of parent	2,646,732	1,695,620
Total shareholders' equity	2,646,732	1,695,620
Total liabilities and shareholders' equity	3,016,840	1,923,456

(2) Condensed quarterly consolidated statements of profit or loss and condensed quarterly consolidated statements of comprehensive income

Condensed quarterly consolidated statements of profit or loss

	(Thousands of yen)	
	Nine months ended September 30, 2023	
	Nine months ended September 30, 2024	
Revenue	30,567	17,159
Business expenses		
Cost of sales	9,572	3,905
Research and development expenses	583,655	419,037
Selling, general and administrative expenses	467,876	549,433
Total business expenses	<u>1,061,103</u>	<u>972,375</u>
Operating loss	(1,030,536)	(955,216)
Other income and expenses		
Finance income	10,296	5,324
Finance costs	(7,197)	(5,957)
Loss on retirement of fixed assets	-	(52,615)
Other income (expenses)	351	8,776
Total other income and expenses	<u>3,450</u>	<u>(44,472)</u>
Loss before tax	<u>(1,027,086)</u>	<u>(999,688)</u>
Net loss	<u>(1,027,086)</u>	<u>(999,688)</u>
Loss attributable to		
Owners of parent	(1,027,086)	(999,688)
Net loss per share		
Basic loss per share (Yen)	(18.53)	(17.76)
Diluted loss per share (Yen)	(18.53)	(17.76)

Condensed quarterly consolidated statements of comprehensive income

	(Thousands of yen)	
	Nine months ended September 30, 2023	
	Nine months ended September 30, 2024	
Net loss	(1,027,086)	(999,688)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	34,877	2,862
Total other comprehensive income	<u>34,877</u>	<u>2,862</u>
Comprehensive income (loss)	<u>(992,209)</u>	<u>(996,826)</u>
Comprehensive income (loss) attributable to		
Owners of parent	(992,209)	(996,826)

(3) Condensed quarterly consolidated statements of changes in equity

Nine months ended September 30, 2023

(Thousands of yen)

	Share capital	Capital surplus	Accumulated deficit	Other components of equity	Total equity attributable to owners of parent	Total
Balance as of January 1, 2023	2,066,706	27,526,853	(24,180,654)	(1,463,370)	3,949,535	3,949,535
Net loss			(1,027,086)		(1,027,086)	(1,027,086)
Exchange differences on translation of foreign operations				34,877	34,877	34,877
Comprehensive income (loss)	–	–	(1,027,086)	34,877	(992,209)	(992,209)
Share-based compensation expense		33,613			33,613	33,613
Issuance of new shares	74,407	74,407			148,814	148,814
Issuance cost of new shares		(1,162)			(1,162)	(1,162)
Total transactions with owners	74,407	106,858	–	–	181,265	181,265
Balance as of September 30, 2023	2,141,113	27,633,711	(25,207,740)	(1,428,493)	3,138,591	3,138,591

Nine months ended September 30, 2024

(Thousands of yen)

	Share capital	Capital surplus	Accumulated deficit	Other components of equity	Total equity attributable to owners of parent	Total
Balance as of January 1, 2024	2,141,113	27,638,335	(25,670,256)	(1,462,460)	2,646,732	2,646,732
Net loss			(999,688)		(999,688)	(999,688)
Exchange differences on translation of foreign operations				2,862	2,862	2,862
Comprehensive income (loss)	–	–	(999,688)	2,862	(996,826)	(996,826)
Share-based compensation expense		21,228			21,228	21,228
Issuance of new shares	14,594	14,594			29,188	29,188
Capital reduction	(2,131,113)	184,647	1,946,466		–	–
Issuance cost of new shares		(4,702)			(4,702)	(4,702)
Total transactions with owners	(2,116,519)	215,767	1,946,466	–	45,714	45,714
Balance as of September 30, 2024	24,594	27,854,102	(24,723,478)	(1,459,598)	1,695,620	1,695,620

(4) Condensed quarterly consolidated statements of cash flows

	(Thousands of yen)	
	Nine months ended September 30, 2023	Nine months ended September 30, 2024
Cash flows from operating activities		
Net loss	(1,027,086)	(999,688)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	63,668	48,322
Impairment losses	–	5,590
Share-based compensation expense	33,613	21,228
Loss (gain) on sale and retirement of fixed assets	2,026	52,615
Finance income	(10,296)	(5,324)
Finance costs	7,197	5,957
Change in operating assets and liabilities		
Trade receivables	(431)	931
Other current assets	18,971	(21,526)
Other current liabilities	(160)	(520)
Trade payables	6,611	(22,254)
Accrued liabilities	(122,126)	(36,549)
Accrued compensation	(29,847)	(10,651)
Other assets	17,115	16,755
Subtotal	(1,040,745)	(945,114)
Interest paid	(7,072)	(5,974)
Net cash provided by (used in) operating activities	(1,047,817)	(951,088)
Cash flows from investing activities		
Interest received	10,238	6,156
Purchase of property, plant and equipment	(24,478)	(35,401)
Proceeds from refund of leasehold and guarantee deposits	816	413
Payment of leasehold and guarantee deposits	(7,137)	–
Cash flows from investing activities	(20,561)	(28,832)
Cash flows from financing activities		
Proceeds from issuance of ordinary shares	148,368	29,080
Proceeds from issuance of share acquisition rights	–	1,120
Payment of lease liabilities	(37,452)	(78,989)
Net cash provided by (used in) financing activities	110,916	(48,789)
Effect of exchange rate changes on cash and cash equivalents	39,892	1,181
Net increase (decrease) in cash and cash equivalents	(917,570)	(1,027,528)
Cash and cash equivalents at beginning of period	4,048,969	2,767,639
Cash and cash equivalents at end of period	3,131,399	1,740,111

(5) Notes to condensed quarterly consolidated financial statements

Notes on going concern assumption

Not applicable.

Segment information, etc.

The Group is engaged in the drug and medical device business and the related businesses which comprise a single segment. Hence segment information is omitted.

Other income and expenses

At a meeting held on July 17, 2024, the Board of Directors of the Company resolved to transfer to the Company the research and development, as well as its administration, conducted at its wholly owned subsidiary in the U.S., Kubota Vision Inc. (“KV”). In conjunction with this transfer, in September 2024, the Company concluded an agreement to terminate the office lease agreement for KV on December 31, 2024. Therefore, the Company recorded ¥52,615 thousand as loss on retirement of fixed assets for the nine months ended September 30, 2024.

Significant subsequent events

Not applicable.