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November 14, 2023

Consolidated Financial Results for the Nine Months Ended September 30, 2023 (under IFRS)

Company name: Kubota Pharmaceutical Holdings Co., Ltd.
 Listing: Tokyo Stock Exchange
 Securities code: 4596
 URL: <https://www.kubotaholdings.co.jp/en/>
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 Scheduled date of the submission of quarterly securities report: November 14, 2023
 Scheduled date to commence dividend payments: –
 Preparation of supplementary material on quarterly financial results: Yes
 Holding of quarterly 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, 2023 (January 1, 2023 to September 30, 2023)

(1) Consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Revenue		Operating profit		Profit before tax		Net profit	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Nine months ended								
September 30, 2023	31	965.5	(1,031)	–	(1,027)	–	(1,027)	–
September 30, 2022	3	–	(1,653)	–	(1,681)	–	(1,681)	–

	Profit attributable to owners of parent		Total comprehensive income		Basic earnings per share	Diluted earnings per share
	Millions of yen	%	Millions of yen	%	Yen	Yen
Nine months ended						
September 30, 2023	(1,027)	–	(992)	–	(18.53)	(18.53)
September 30, 2022	(1,681)	–	(1,293)	–	(35.20)	(35.20)

(2) Consolidated financial position

	Total assets	Total shareholders' equity	Equity attributable to owners of parent	Ratio of equity attributable to owners of parent
	Millions of yen	Millions of yen	Millions of yen	%
As of				
September 30, 2023	3,510	3,139	3,139	89.4
December 31, 2022	4,420	3,950	3,950	89.4

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, 2022	Yen –	Yen 0.00	Yen –	Yen 0.00	Yen 0.00
Fiscal year ending December 31, 2023	–	0.00	–		
Fiscal year ending December 31, 2023 (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, 2023 (January 1, 2023 to December 31, 2023)

The earnings forecasts for the fiscal year ending December 31, 2023, are not shown because they cannot be reasonably calculated at this time. Please refer to “1. Qualitative Information Regarding Financial Results for the Nine Months Ended September 30, 2023, (3) Explanation of consolidated earnings forecasts and other forward-looking statements” on page 4 of the attached materials for details concerning the reasons.

*** Notes**

- (1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in the change in scope of consolidation): 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, 2023	56,062,988 shares
As of December 31, 2022	54,622,588 shares

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

As of September 30, 2023	71 shares
As of December 31, 2022	70 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, 2023	55,435,721 shares
For the nine months ended September 30, 2022	47,752,421 shares

- * Quarterly financial results reports are exempt from quarterly reviews conducted by certified public accountants or an audit corporation.

- * 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. Qualitative Information Regarding Financial Results for the Nine Months Ended September 30, 2023, (3) Explanation of consolidated earnings forecasts and other forward-looking statements" on page 4 of the attached materials for matters relating to earnings forecasts.

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1. Qualitative Information Regarding Financial Results for the Nine Months Ended September 30, 2023

(1) Explanation of operating results

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 month ended September 30, 2023, the global economy was expected to pick up due to the drop in new cases of COVID-19, but the situation still remains unpredictable; in addition, there is uncertainty about the future due to soaring raw materials and transportation costs as a result of energy problems and other consequences of the prolonged Ukraine conflict, rapid exchange rate fluctuations, and other factors.

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. (“Kubota Vision”), 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, Kubota Vision 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 preparation for sales expansion while continuing clinical studies aimed at obtaining more evidence and other activities. The Group’s policy going forward is to strengthen marketing activities in Japan and proactively collaborate with other companies, which will lead to business growth.

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. From January 2023, the Group has been exploring the possibility of joint development and commercialization with partner companies while verifying the ideal working model through 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.

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, 2023, revenue was ¥31 million, an increase of 965.5% year on year, and cost of sales was ¥10 million, an increase of 263.6% 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, 2023, was ¥584 million, a decrease of ¥722 million, or 55.3%, year on year. This was mainly due to decreases in development expenses for emixustat and the wearable myopia control device.

(Unit: Thousands of yen or %)

	Nine months ended September 30, 2022	Nine months ended September 30, 2023	Increase (Decrease)	Change (%)
Research and development expenses	1,305,802	583,655	(722,147)	(55.3)

Selling, general and administrative expenses

Selling, general and administrative expenses for the nine months ended September 30, 2023, was ¥468 million, an increase of ¥46 million, or 11.0%, year on year. This was mainly due to increases in patent-related expenses year on year.

(Unit: Thousands of yen or %)

	Nine months ended September 30, 2022	Nine months ended September 30, 2023	Increase (Decrease)	Change (%)
Selling, general and administrative expenses	421,391	467,876	46,484	11.0

(2) Explanation of financial position

Current assets

Current assets as of the end of the third quarter of the current fiscal year was ¥3,272 million, a decrease of ¥910 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 ¥238 million, an increase of ¥0 million from the end of the previous fiscal year. This was mainly due to an increase in property, plant and equipment, despite a decrease in other non-current assets.

Current liabilities

Current liabilities as of the end of the third quarter of the current fiscal year was ¥264 million, a decrease of ¥97 million from the end of the previous fiscal year. This was mainly due to decreases in accrued liabilities and accrued compensation.

Non-current liabilities

Non-current liabilities as of the end of the third quarter of the current fiscal year was ¥108 million, a decrease of ¥2 million from the end of the previous fiscal year. This was due to a decrease in lease liabilities.

Shareholders' equity

Shareholders' equity as of the end of the third quarter of the current fiscal year was ¥3,139 million, a decrease of ¥811 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) Explanation of consolidated earnings forecasts and other forward-looking statements

Revenue from sales of Kubota Glass, which utilizes Kubota Glass technology, the Group's original active stimulation technology, 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, 2023, 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, 2022	(Thousands of yen) As of September 30, 2023
Assets		
Current assets		
Cash and cash equivalents	4,048,969	3,131,399
Trade receivables	3,436	4,138
Inventories	7,433	14,655
Other current assets	121,997	122,009
Total current assets	4,181,835	3,272,201
Non-current assets		
Property, plant and equipment	203,849	219,916
Other non-current assets	34,071	18,205
Total non-current assets	237,920	238,121
Total assets	4,419,755	3,510,322
Liabilities and equity		
Liabilities		
Current liabilities		
Trade payables	42,928	55,120
Accrued liabilities	194,447	89,779
Accrued compensation	76,247	52,131
Lease liabilities	39,175	57,815
Other current liabilities	8,030	9,376
Total current liabilities	360,827	264,221
Non-current liabilities		
Lease liabilities	109,393	107,510
Total non-current liabilities	109,393	107,510
Total liabilities	470,220	371,731
Shareholders' equity		
Share capital	2,066,706	2,141,113
Capital surplus	27,526,853	27,633,711
Retained earnings (loss)	(24,180,654)	(25,207,740)
Other components of equity	(1,463,370)	(1,428,493)
Total equity attributable to owners of parent	3,949,535	3,138,591
Total shareholders' equity	3,949,535	3,138,591
Total liabilities and shareholders' equity	4,419,755	3,510,322

(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

Nine months ended September 30, 2022 and 2023

	Nine months ended September 30, 2022	(Thousands of yen) Nine months ended September 30, 2023
Revenue	2,869	30,567
Business expenses		
Cost of sales	2,632	9,572
Research and development expenses	1,305,802	583,655
Selling, general and administrative expenses	421,391	467,876
Total business expenses	<u>1,729,825</u>	<u>1,061,103</u>
Other operating income	73,706	-
Operating loss	(1,653,250)	(1,030,536)
Other income and expenses		
Finance income	10,544	10,296
Finance costs	(9,010)	(7,197)
Other income (expenses)	(29,153)	351
Total other income and expenses	<u>(27,619)</u>	<u>3,450</u>
Loss before tax	(1,680,869)	(1,027,086)
Net loss	<u>(1,680,869)</u>	<u>(1,027,086)</u>
Loss attributable to		
Owners of parent	(1,680,869)	(1,027,086)
Net loss per share		
Basic loss per share (Yen)	(35.20)	(18.53)
Diluted loss per share (Yen)	(35.20)	(18.53)

Condensed quarterly consolidated statements of comprehensive income

Nine months ended September 30, 2022 and 2023

	Nine months ended September 30, 2022	(Thousands of yen) Nine months ended September 30, 2023
Net loss	(1,680,869)	(1,027,086)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	388,148	34,877
Total other comprehensive income	<u>388,148</u>	<u>34,877</u>
Comprehensive income	<u>(1,292,721)</u>	<u>(992,209)</u>
Comprehensive income attributable to		
Owners of parent	(1,292,721)	(992,209)

(3) Condensed quarterly consolidated statements of changes in equity

Nine months ended September 30, 2022

(Thousands of yen)

	Share capital	Capital surplus	Retained earnings (loss)	Other components of equity	Total equity attributable to owners of parent	Total
Balance as of January 1, 2022	1,308,902	26,755,419	(22,164,748)	(1,746,652)	4,152,921	4,152,921
Net loss			(1,680,869)		(1,680,869)	(1,680,869)
Exchange differences on translation of foreign operations				388,148	388,148	388,148
Comprehensive income	–	–	(1,680,869)	388,148	(1,292,721)	(1,292,721)
Share-based compensation expense		12,837			12,837	12,837
Issuance of new shares	607,740	607,740			1,215,480	1,215,480
Issuance cost of new shares		(5,441)			(5,441)	(5,441)
Total transactions with owners	607,740	615,136	–	–	1,222,876	1,222,876
Balance as of September 30, 2022	1,916,642	27,370,555	(23,845,617)	(1,358,504)	4,083,076	4,083,076

Nine months ended September 30, 2023

(Thousands of yen)

	Share capital	Capital surplus	Retained earnings (loss)	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	–	–	(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

(4) Condensed quarterly consolidated statements of cash flows

	(Thousands of yen)	
	Nine months ended September 30, 2022	Nine months ended September 30, 2023
Cash flows from operating activities		
Net loss	(1,680,869)	(1,027,086)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	42,330	63,668
Share-based compensation expense	12,837	33,613
Amortization of premium or discount on securities	(1,461)	-
Loss (gain) on sale and retirement of fixed assets	(2,247)	2,026
Finance income	(10,544)	(10,296)
Finance costs	9,010	7,197
Change in operating assets and liabilities		
Trade receivables	(3,713)	(431)
Other current assets	100,847	18,971
Other current liabilities	-	(160)
Trade payables	(16,229)	6,611
Accrued liabilities	(89,560)	(122,126)
Accrued compensation	(27,154)	(29,847)
Deferred rent, lease incentives, and others	(11,849)	-
Other assets	8,757	17,115
Subtotal	(1,669,845)	(1,040,745)
Interest paid	(8,776)	(7,072)
Net cash provided by (used in) operating activities	(1,678,621)	(1,047,817)
Cash flows from investing activities		
Interest received	9,000	10,238
Purchase of other financial assets	(581,342)	-
Proceeds from redemption upon maturity of other financial assets	1,102,520	-
Purchase of property, plant and equipment	(1,646)	(24,478)
Proceeds from collection of lease receivables	24,954	-
Proceeds from refund of leasehold and guarantee deposits	12,598	816
Payment of leasehold and guarantee deposits	-	(7,137)
Net cash provided by (used in) investing activities	566,084	(20,561)
Cash flows from financing activities		
Proceeds from issuance of ordinary shares	1,212,454	148,368
Proceeds from issuance of share acquisition rights	3,100	-
Payment of lease liabilities	(54,922)	(37,452)
Net cash provided by (used in) financing activities	1,160,632	110,916
Effect of exchange rate changes on cash and cash equivalents	347,239	39,892
Net increase (decrease) in cash and cash equivalents	395,334	(917,570)
Cash and cash equivalents at beginning of period	3,977,312	4,048,969
Cash and cash equivalents at end of period	4,372,646	3,131,399

(5) Notes to condensed quarterly consolidated financial statements

Notes on going concern assumption

Not applicable.

Significant subsequent events

Not applicable.