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August 14, 2024

Consolidated Financial Results for the Six Months Ended June 30, 2024 (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 semi-annual securities report: August 14, 2024
 Scheduled date to commence dividend payments: –
 Preparation of supplementary material on financial results: Yes
 Holding of financial results presentation meeting: Yes (for institutional investors and analysts)

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

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

(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	%
Six months ended June 30, 2024	10	(43.2)	(675)	–	(669)	–	(669)	–
Six months ended June 30, 2023	17	–	(747)	–	(745)	–	(745)	–

	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
Six months ended June 30, 2024	(669)	–	(652)	–	(11.90)	(11.90)
Six months ended June 30, 2023	(745)	–	(721)	–	(13.48)	(13.48)

(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 June 30, 2024	2,343	2,029	2,029	86.6
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. Qualitative Information Regarding Financial Results for the Six Months Ended June 30, 2024, (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) 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 June 30, 2024	56,298,188 shares
As of December 31, 2023	56,062,988 shares

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

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

(iii) Average number of shares outstanding during the period

For the six months ended June 30, 2024	56,228,898 shares
For the six months ended June 30, 2023	55,247,459 shares

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

* Proper use of earnings forecasts, and other special items

(Cautions on forward-looking statements, etc.)

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 Six Months Ended June 30, 2024, (3) Explanation of consolidated earnings forecasts and other forward-looking statements" on page 4 of the attached materials for matters relating to earnings forecasts.

(Means of obtaining the presentation material on financial statements)

The Company is planning to hold a financial results presentation meeting (WEB conference, in Japanese only, recorded and available on the Company's website at a later date) for institutional investors and analysts on August 27, 2024.

The Company also plans to post presentation materials (in English and Japanese) for the financial results and the recorded WEB conference available on the Company's website.

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1. Qualitative Information Regarding Financial Results for the Six Months Ended June 30, 2024

(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. The Group aims to be a big data company by promoting the digitalization of the field of ophthalmology in order to eradicate blindness from the world.

During the six months ended June 30, 2024, 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 development of its business and research and development as follows.

Medical devices

Wearable myopia control device (Kubota Glass)

Kubota Glass technology, being developed by the Group, 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 the future, the Group aims to apply this technology to other devices to come closer to realizing the slowing of myopia. In 2022, the Group published a paper in Scientific Reports, issued by Springer Nature, on a clinical study of its desktop device in adults. The Group believes that this application of 1.5 hours of defocus stimulation five times a week is the first time that the potential for slowing myopia has been demonstrated in adults, where the effects are less visible than in children. In 2021, the Group received medical device registration approval in Taiwan, and in 2022, completed the registration of medical devices with the U.S. FDA. 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 establish a new Business Development office, strengthen marketing activities in Japan and proactively collaborate with other companies, which will lead to business growth. In addition, the Group will continue with its soft launch in Japan, the U.S., and Taiwan for the purpose of troubleshooting with regard to the processes including manufacturing, sales and distribution, ongoing customer support, and verifying market fit. At the same time, the Group plans to use a sequential approach to strengthen its marketing activities in preparation for commercialization in the wider market and prepare for the development of next-generation models that better meet market needs. In addition, Kubota Glass, sold by the Group, was launched in Japan in 2022, and in July of this year, the Group executed a purchase agreement with Sojitz Kyushu Corporation (Fukuoka City, Fukuoka Prefecture) with a view to exporting and selling Kubota Glass in China. In August of the same year, the Group has entered into a business partnership agreement with the company to expand the sales of Kubota Glass in the Chinese market. The two parties have commenced collaboration under this agreement. Under this agreement, both parties will leverage their respective areas of expertise and management resources to collaborate on the joint development of products and technologies, market expansion, distribution channel development, and business development. This partnership aims to promote mutual growth and cooperation in these areas.

Home-based and remote medical monitoring device

The Group is developing eyeMO, 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. In December 2023, the Group executed a collaboration letter of intent with AUROLAB (Madurai, India), which serves as the manufacturing facility of Aravind Eye Care Hospital (AECS)—one of the most prestigious eye hospitals worldwide—for the purpose of joint development. AECS has 14 eye hospitals, 6 outpatient eye examination centers, and 108 initial eye care facilities in southern India, and is one of the leading companies in the world, performing over 4.5 million surgeries and treatments annually. At the same time, the Group executed a vendor agreement with IQVIA Services Japan G.K. (Minato-ku, Tokyo) for a specific clinical study to be funded by Chugai Pharmaceutical Co., Ltd. In this study, medical professionals will verify whether the device can

be used in patients with diabetic macular edema in their homes and determine the validity of retinal thickness measurements and measurements of retinal status for identifying the presence of intra- and subretinal edema. A feasibility study will be conducted prior to this study.

Small molecule compounds

With regard to emixustat hydrochloride (“emixustat”), the phase 3 clinical study for Stargardt disease (194 subjects) that started in November 2018 ended without achieving the primary endpoint, among others, but further post-study analysis subsequently revealed statistical efficacy in a group of subjects in the early stages of disease onset. The safety and tolerability of emixustat remains unchanged and was found to remain consistent with the results of prior clinical studies.

Results of a post-study analysis of emixustat’s efficacy suggested that, when comparing the subject group with a smaller atrophic lesion area at the baseline time against the group that received the placebo, emixustat significantly ($p=0.0206$) reduced the expansion (= worsening) of the atrophic lesion at two years in the group receiving emixustat. This result clearly demonstrates that emixustat is effective for a specific group of subjects, which is an important finding for future treatment strategies. The Group are in the process of submitting detailed phase 3 results to a peer-reviewed ophthalmology journal and will provide further information on the efficacy and safety of emixustat in selected groups of Stargardt disease patients once the results have been accepted. The Group plans to continue its activities, such as searching for co-development partners, while reconsidering its future plans for emixustat.

For the six months ended June 30, 2024, revenue was ¥10 million, a decrease of 43.2% year on year, and cost of sales was ¥2 million, a decrease of 65.8% 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 six months ended June 30, 2024, was ¥305 million, a decrease of ¥133 million, or 30.3%, 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 %)

	Six months ended June 30, 2023	Six months ended June 30, 2024	Increase (Decrease)	Change (%)
Research and development expenses	437,657	305,065	(132,592)	(30.3)

Selling, general and administrative expenses

Selling, general and administrative expenses for the six months ended June 30, 2024, was ¥378 million, an increase of ¥57 million, or 17.8%, year on year. This was mainly due to increases in paid compensation, among others, associated with Kubota Glass and audit fees, etc., despite a decrease in patent-related expenses.

(Unit: Thousands of yen or %)

	Six months ended June 30, 2023	Six months ended June 30, 2024	Increase (Decrease)	Change (%)
Selling, general and administrative expenses	320,718	377,814	57,096	17.8

(2) Explanation of financial position

Current assets

Current assets at the end of the six months ended June 30, 2024 was ¥2,185 million, a decrease of ¥685 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 at the end of the six months ended June 30, 2024 was ¥158 million, an increase of ¥11 million from the end of the previous fiscal year. This was mainly due to an increase in property, plant and equipment.

Current liabilities

Current liabilities at the end of the six months ended June 30, 2024 was ¥249 million, a decrease of ¥33 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 at the end of the six months ended June 30, 2024 was ¥64 million, a decrease of ¥23 million from the end of the previous fiscal year. This was due to an increase in lease liabilities.

Shareholders' equity

Shareholders' equity at the end of the six months ended June 30, 2024 was ¥2,029 million, a decrease of ¥618 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 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 Semi-annual Consolidated Financial Statements and Significant Notes Thereto

(1) Condensed semi-annual consolidated statements of financial position

	As of December 31, 2023	(Thousands of yen) As of June 30, 2024
Assets		
Current assets		
Cash and cash equivalents	2,767,639	2,063,057
Trade receivables	1,964	-
Inventories	36,849	61,298
Other current assets	62,989	60,550
Total current assets	2,869,441	2,184,905
Non-current assets		
Property, plant and equipment	129,457	139,449
Other non-current assets	17,942	18,450
Total non-current assets	147,399	157,899
Total assets	3,016,840	2,342,804
Liabilities and equity		
Liabilities		
Current liabilities		
Trade payables	34,547	28,642
Accrued liabilities	110,085	82,693
Accrued compensation	72,276	59,878
Lease liabilities	55,659	65,897
Other current liabilities	10,347	12,346
Total current liabilities	282,914	249,456
Non-current liabilities		
Lease liabilities	87,194	64,443
Total non-current liabilities	87,194	64,443
Total liabilities	370,108	313,899
Shareholders' equity		
Share capital	2,141,113	19,562
Capital surplus	27,638,335	27,848,033
Retained earnings (loss)	(25,670,256)	(24,392,725)
Other components of equity	(1,462,460)	(1,445,965)
Total equity attributable to owners of parent	2,646,732	2,028,905
Total shareholders' equity	2,646,732	2,028,905
Total liabilities and shareholders' equity	3,016,840	2,342,804

(2) Condensed semi-annual consolidated statements of profit or loss and condensed semi-annual consolidated statements of comprehensive income

Condensed semi-annual consolidated statements of profit or loss

	Six months ended June 30, 2023	(Thousands of yen) Six months ended June 30, 2024
Revenue	17,232	9,785
Business expenses		
Cost of sales	6,141	2,100
Research and development expenses	437,657	305,065
Selling, general and administrative expenses	320,718	377,814
Total business expenses	764,516	684,979
Operating loss	(747,284)	(675,194)
Other income and expenses		
Finance income	7,007	4,392
Finance costs	(4,799)	(4,082)
Other income (expenses)	386	5,949
Total other income and expenses	2,594	6,259
Loss before tax	(744,690)	(668,935)
Net loss	(744,690)	(668,935)
Loss attributable to Owners of parent	(744,690)	(668,935)
Net loss per share		
Basic loss per share (Yen)	(13.48)	(11.90)
Diluted loss per share (Yen)	(13.48)	(11.90)

Condensed semi-annual consolidated statements of comprehensive income

	Six months ended June 30, 2023	(Thousands of yen) Six months ended June 30, 2024
Net loss	(744,690)	(668,935)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	23,205	16,495
Total other comprehensive income	23,205	16,495
Comprehensive income	(721,485)	(652,440)
Comprehensive income attributable to Owners of parent	(721,485)	(652,440)

(3) Condensed semi-annual consolidated statements of changes in equity

Six months ended June 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			(744,690)		(744,690)	(744,690)
Exchange differences on translation of foreign operations				23,205	23,205	23,205
Comprehensive income	–	–	(744,690)	23,205	(721,485)	(721,485)
Share-based compensation expense		23,648			23,648	23,648
Issuance of new shares	56,551	56,551			113,102	113,102
Issuance cost of new shares		(816)			(816)	(816)
Total transactions with owners	56,551	79,383	–	–	135,934	135,934
Balance as of June 30, 2023	2,123,257	27,606,236	(24,925,344)	(1,440,165)	3,363,984	3,363,984

Six months ended June 30, 2024

(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, 2024	2,141,113	27,638,335	(25,670,256)	(1,462,460)	2,646,732	2,646,732
Net loss			(668,935)		(668,935)	(668,935)
Exchange differences on translation of foreign operations				16,495	16,495	16,495
Comprehensive income	–	–	(668,935)	16,495	(652,440)	(652,440)
Share-based compensation expense		15,537			15,537	15,537
Issuance of new shares	9,562	9,562			19,124	19,124
Capital reduction	(2,131,113)	184,647	1,946,466		–	–
Issuance cost of new shares		(48)			(48)	(48)
Total transactions with owners	(2,121,551)	209,698	1,946,466	–	34,613	34,613
Balance as of June 30, 2024	19,562	27,848,033	(24,392,725)	(1,445,965)	2,028,905	2,028,905

(4) Condensed semi-annual consolidated statements of cash flows

	Six months ended June 30, 2023	(Thousands of yen) Six months ended June 30, 2024
Cash flows from operating activities		
Net loss	(744,690)	(668,935)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	41,599	31,722
Impairment losses	–	5,590
Share-based compensation expense	23,648	15,537
Loss (gain) on sale and retirement of fixed assets	2,026	–
Finance income	(7,007)	(4,392)
Finance costs	4,799	4,082
Change in operating assets and liabilities		
Trade receivables	1,724	2,136
Other current assets	23,081	(8,429)
Other current liabilities	3,953	567
Trade payables	(5,543)	(10,469)
Accrued liabilities	(69,602)	(40,727)
Accrued compensation	(25,912)	(20,265)
Other assets	18,349	1,820
Subtotal	(733,575)	(691,763)
Interest paid	(4,715)	(4,047)
Net cash provided by (used in) operating activities	(738,290)	(695,810)
Cash flows from investing activities		
Interest received	7,166	5,054
Purchase of property, plant and equipment	(13,665)	(30,771)
Net cash provided by (used in) investing activities	(6,499)	(25,717)
Cash flows from financing activities		
Proceeds from issuance of ordinary shares	112,778	19,051
Payment of lease liabilities	(26,984)	(30,192)
Net cash provided by (used in) financing activities	85,794	(11,141)
Effect of exchange rate changes on cash and cash equivalents	24,228	28,086
Net increase (decrease) in cash and cash equivalents	(634,767)	(704,582)
Cash and cash equivalents at beginning of period	4,048,969	2,767,639
Cash and cash equivalents at end of period	3,414,202	2,063,057

(5) Notes to condensed semi-annual consolidated financial statements

Notes on going concern assumption

Not applicable.

Significant subsequent events

(Decision to rationalize management by transferring research and development and its administrative base from the U.S. to Japan)

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”).

The Company is expanding revenue through product and service offerings and the out-licensing and marketing of its pipeline, as well as investing in its current pipeline of emixustat hydrochloride, eyeMO (PBOS), and wearable myopia glasses (Kubota Glass). The Company recognizes that its medium- to long-term management challenge is to continue discovering and establishing new pipelines while optimizing the balance between the revenues generated by these pipelines with investment and administrative costs.

Among administrative costs, the cost of maintaining the U.S. base, when converted to yen, has been growing year by year due to recent inflation and exchange rate fluctuations in the U.S., which has significantly impacted the management of the Company. The effects of U.S. inflation and the depreciation of the yen are uncertain, and this trend of increasing costs may continue.

Since its establishment, the Company has established human network infrastructure through the promotion of U.S.-based research and development and accumulation of know-how that enables it to acquire industry information, trends, and highly specialized human resources, thus providing the Company with access to people, information, facilities, and other resources around the world with which it can conduct research and development as needed. This decision was made because the establishment of said structure has enabled the transfer of research and development as well as its administrative base to Japan without any major impairment of research and development.

The Company will establish an efficient administrative structure by integrating the research and development function transferred from KV, as well as its administrative function, with the Company’s existing administrative functions.

The following cost reductions will be implemented. The Company does not believe that this rationalization will have a material impact on research and development or other areas, and will continue to focus on growth. The U.S. corporation will continue to exist.

- Reorganization of personnel in the U.S. (current operations will be taken over by the Company in stages, with rationalization expected to be completed by the end of March 2025 at the latest)
- Termination of the current office contract (the current office is expected to be vacated at the end of 2024)
- When selecting research and development partners, priority will be placed on those located in Japan, with contracts only being made with partners in other countries when necessary (based on the terms of each contract, the transition to the new structure is expected to be completed by the end of 2024)

This management rationalization is not expected to impact sales. As a result of this management rationalization, the Company expects that research and development expenses for the fiscal year ending December 31, 2025 will be reduced by approximately ¥400 million per year compared to the fiscal year ended December 31, 2023, and selling, general and administrative expenses will be reduced by approximately ¥60 million per year compared to the fiscal year ended December 31, 2023. However, the Company reasonably estimates that it will incur expenses and losses (e.g., paid commission and compensation, etc.) for the fiscal year ending December 31, 2024 in connection with the management rationalization described above in the amount of approximately ¥40 million. These estimated reductions do not take into account the impact of additional investments, etc., after rationalization.