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August 12, 2022

Consolidated Financial Results for the Six Months Ended June 30, 2022 (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: August 12, 2022
 Scheduled date to commence dividend payments: –
 Preparation of supplementary material on quarterly financial results: Yes
 Holding of quarterly 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, 2022 (January 1, 2022 to June 30, 2022)

(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, 2022	–	–	(1,172)	–	(1,197)	–	(1,197)	–
June 30, 2021	–	–	(1,335)	–	(1,351)	–	(1,351)	–

	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, 2022	(1,197)	–	(888)	–	(26.02)	(26.02)
June 30, 2021	(1,351)	–	(1,077)	–	(29.86)	(29.86)

(2) Consolidated financial position

As of	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	%
June 30, 2022	4,563	3,892	3,892	85.3
December 31, 2021	4,833	4,153	4,153	85.9

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, 2021	Yen –	Yen 0.00	Yen –	Yen 0.00	Yen 0.00
Fiscal year ending December 31, 2022	–	0.00			
Fiscal year ending December 31, 2022 (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, 2022 (January 1, 2022 to December 31, 2022)

(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	%
Full year	–	–	(2,000)	–	(2,000)	–	(2,000)	–

	Profit attributable to owners of parent		Basic earnings per share
	Millions of yen	%	Yen
Full year	(2,000)	–	(43.61)

(Note) Revisions to the earnings forecasts most recently announced: None

*** 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 June 30, 2022	48,862,288 shares
As of December 31, 2021	45,861,688 shares

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

As of June 30, 2022	70 shares
As of December 31, 2021	70 shares

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

For the six months ended June 30, 2022	45,992,724 shares
For the six months ended June 30, 2021	45,242,597 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

(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, 2022, (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 quarterly financial statements)

The Company is planning to hold a quarterly 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 24, 2022.

The Company also plans to post presentation materials (in English and Japanese) for the quarterly 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, 2022

(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.

In the global economy during the six months ended June 30, 2022, the outlook remains uncertain due to the further spread of the novel coronavirus disease (COVID-19) and other factors.

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

Small molecule compounds

With regard to emixustat hydrochloride (“emixustat”), the Group started a phase 3 clinical study for Stargardt disease in November 2018, and the study was ongoing across 29 sites in 11 countries worldwide until June 2022. For the clinical study, the subjects were randomly assigned to a group receiving emixustat or a group receiving a placebo at a 2:1 ratio. Emixustat (10 mg) or the placebo was administered orally once a day for 24 months. The primary endpoint was to determine if emixustat reduced the rate of macular atrophy progression in subjects with Stargardt disease (juvenile macular degeneration) and the secondary endpoints included additional imaging parameters such as best corrected visual acuity (BCVA), contrast sensitivity and reading speed, and changes in several visual functions.

Although the initial target for the study was 162 subjects, the Group increased the number of enrolled subjects to 194 in light of the impact of the spread of COVID-19 and other factors. In addition, the last patient last visit (LPLV) was completed on June 23, 2022 (U.S. time), thereby concluding this phase 3 clinical study.

For the results of the aggregation and analysis of the database for the phase 3 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, tolerability of emixustat was good and the safety profile was consistent with that observed in prior research.

As a result, the Company plans to examine the data obtained from the phase 3 clinical study more closely and continue its activities, such as searching for co-development partners, while reconsidering its future plans for emixustat.

Medical devices

With regard to Kubota GlassTM, a wearable myopia control device aimed at treating and controlling the progression of myopia utilizing the Group’s original active stimulation technology, in 2020, proof-of-concept (POC) clinical studies using a desktop device and a wearable device demonstrated that axial length (the distance from the cornea to the retina) decreased in the test eye compared to the control eye. Following the completion of the initial prototype in December 2020, 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 the second quarter of the current fiscal year, the Group completed the registration of medical devices with the U.S. FDA and began sales at some ophthalmic clinics in the U.S. as a soft launch. The Group is proceeding with preparation for sales expansion while continuing clinical studies aimed at obtaining more evidence, and other activities. Going forward, the Group will conduct a soft launch in the U.S., Japan, and Taiwan for the purpose of troubleshooting with regard to the processes including manufacturing, sales and distribution, and aftercare, and verifying market fit. At the same time, the Group plans to use a sequential approach to strengthen its marketing activities in readiness for commercialization in the wider market and prepare for the development of next-generation models that better meet market needs.

The Patient Based Ophthalmology Suite (PBOS) is a remote retinal monitoring device that makes it possible to check the condition of patients’ retinas at their home. Since the initial prototype was completed in July 2020, the Group has continued to improve its functions and is exploring the possibility

of joint development and commercialization with partner companies while making software improvements, such as 3D imaging capabilities using artificial intelligence (AI).

The Group also has worked to develop a compact optical coherence tomography (OCT) device that can be carried on National Aeronautics and Space Administration (NASA)'s manned mission to Mars. Phase 1 of the project was completed in April 2020. Discussions regarding the details of Phase 2 of this project continue, but the timing of its commencement has not been decided.

The Group will, for the time being, will focus its management resources on development and sales in this field, centered on Kubota Glass™.

Research and development expenses

Research and development expenses for the six months ended June 30, 2022, was ¥899 million, a decrease of ¥88 million, or 8.9%, year on year. This was mainly due to a decrease in development expenses for the remote retinal monitoring device PBOS, despite an increase in development expenses for emixustat and wearable myopia control devices.

(Unit: Thousands of yen or %)

	Six months ended June 30, 2021	Six months ended June 30, 2022	Increase (Decrease)	Change (%)
Research and development expenses	986,653	898,540	(88,114)	(8.9)

General and administrative expenses

General and administrative expenses for the six months ended June 30, 2022, was ¥274 million, a decrease of ¥75 million, or 21.5%, year on year. This was mainly due to decreases in patent-related expenses and other general and administrative expenses associated with the cost-saving measures, year on year.

(Unit: Thousands of yen or %)

	Six months ended June 30, 2021	Six months ended June 30, 2022	Increase (Decrease)	Change (%)
General and administrative expenses	348,755	273,745	(75,010)	(21.5)

(2) Explanation of financial position

Current assets

Current assets as of the end of the second quarter of the current fiscal year was ¥4,373 million, a decrease of ¥253 million from the end of the previous fiscal year. This was mainly due to decreases in cash and cash equivalents and other financial assets.

Non-current assets

Non-current assets as of the end of the second quarter of the current fiscal year was ¥191 million, a decrease of ¥16 million from the end of the previous fiscal year. This was mainly due to depreciation of property, plant and equipment.

Current liabilities

Current liabilities as of the end of the second quarter of the current fiscal year was ¥552 million, an increase of ¥10 million from the end of the previous fiscal year. This was mainly due to an increase in accrued liabilities despite decreases in trade payables, accrued compensation and lease liabilities.

Non-current liabilities

Non-current liabilities as of the end of the second quarter of the current fiscal year was ¥119 million, a decrease of ¥18 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 second quarter of the current fiscal year was ¥3,892 million, a decrease of ¥261 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

With regard to the earnings forecasts for the fiscal year ending December 31, 2022, that the Group announced on February 14, 2022, the analysis was predicated on the spread of COVID-19 and other factors, and no changes have been made to them at this point.

Although the Group believes that the effects of the spread of COVID-19 and other factors on business performance will be insignificant, it will continue to monitor the situation closely and promptly disclose any expected impact on business performance that arises.

2. Condensed Quarterly Consolidated Financial Statements and Significant Notes Thereto

(1) Condensed quarterly consolidated statements of financial position

	As of December 31, 2021	As of June 30, 2022
(Thousands of yen)		
Assets		
Current assets		
Cash and cash equivalents	3,977,312	3,851,400
Other financial assets	438,582	341,624
Other current assets	209,378	179,595
Total current assets	4,625,272	4,372,619
Non-current assets		
Property, plant and equipment	192,427	174,645
Other non-current assets	14,865	16,169
Total non-current assets	207,292	190,814
Total assets	4,832,564	4,563,433
Liabilities and equity		
Liabilities		
Current liabilities		
Trade payables	75,085	57,233
Accrued liabilities	323,220	400,901
Accrued compensation	70,039	50,262
Deferred rent, lease incentives, and others	11,697	-
Lease liabilities	62,312	43,536
Total current liabilities	542,353	551,932
Non-current liabilities		
Lease liabilities	137,290	119,475
Total non-current liabilities	137,290	119,475
Total liabilities	679,643	671,407
Shareholders' equity		
Share capital	1,308,902	1,613,612
Capital surplus	26,755,419	27,077,404
Retained earnings (loss)	(22,164,748)	(23,361,585)
Other components of equity	(1,746,652)	(1,437,405)
Total equity attributable to owners of parent	4,152,921	3,892,026
Total shareholders' equity	4,152,921	3,892,026
Total liabilities and shareholders' equity	4,832,564	4,563,433

(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

Six months ended June 30, 2021 and 2022

	(Thousands of yen)	
	Six months ended June 30, 2021	Six months ended June 30, 2022
Business expenses		
Research and development expenses	986,653	898,540
General and administrative expenses	348,755	273,745
Total business expenses	1,335,408	1,172,285
Operating loss	(1,335,408)	(1,172,285)
Other income and expenses		
Finance income	8,188	3,669
Finance costs	(10,230)	(6,213)
Other income (expenses)	(13,548)	(22,008)
Total other income and expenses	(15,590)	(24,552)
Loss before tax	(1,350,998)	(1,196,837)
Net loss	(1,350,998)	(1,196,837)
Loss attributable to Owners of parent	(1,350,998)	(1,196,837)
Net loss per share		
Basic loss per share (Yen)	(29.86)	(26.02)
Diluted loss per share (Yen)	(29.86)	(26.02)

Condensed quarterly consolidated statements of comprehensive income

Six months ended June 30, 2021 and 2022

	(Thousands of yen)	
	Six months ended June 30, 2021	Six months ended June 30, 2022
Net loss	(1,350,998)	(1,196,837)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	273,774	309,247
Total other comprehensive income	273,774	309,247
Comprehensive income	(1,077,224)	(887,590)
Comprehensive income attributable to Owners of parent	(1,077,224)	(887,590)

(3) Condensed quarterly consolidated statements of changes in equity

Six months ended June 30, 2021

(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, 2021	1,148,650	26,523,421	(19,548,297)	(2,130,695)	5,993,079	5,993,079
Net loss			(1,350,998)		(1,350,998)	(1,350,998)
Exchange differences on translation of foreign operations				273,774	273,774	273,774
Comprehensive income	-	-	(1,350,998)	273,774	(1,077,224)	(1,077,224)
Share-based compensation expense		57,484			57,484	57,484
Issuance of new shares	121,331	121,331			242,662	242,662
Issuance cost of new shares		(1,318)			(1,318)	(1,318)
Total equity transactions with owners	121,331	177,497	-	-	298,828	298,828
Balance as of June 30, 2021	1,269,981	26,700,918	(20,899,295)	(1,856,921)	5,214,683	5,214,683

Six months ended June 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			(1,196,837)		(1,196,837)	(1,196,837)
Exchange differences on translation of foreign operations				309,247	309,247	309,247
Comprehensive income	-	-	(1,196,837)	309,247	(887,590)	(887,590)
Share-based compensation expense		17,275			17,275	17,275
Issuance of new shares	304,710	304,710			609,420	609,420
Total equity transactions with owners	304,710	321,985	-	-	626,695	626,695
Balance as of June 30, 2022	1,613,612	27,077,404	(23,361,585)	(1,437,405)	3,892,026	3,892,026

(4) Condensed quarterly consolidated statements of cash flows

	(Thousands of yen)	
	Six months ended June 30, 2021	Six months ended June 30, 2022
Cash flows from operating activities		
Net loss	(1,350,998)	(1,196,837)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	29,014	27,591
Share-based compensation expense	57,484	17,275
Amortization of premium or discount on securities	2,623	(1,384)
Loss (gain) on sale and retirement of fixed assets	–	(2,247)
Finance income	(8,188)	(3,669)
Finance costs	10,230	6,213
Change in operating assets and liabilities		
Other current assets	(10,036)	46,967
Trade payables	(32,944)	(26,757)
Accrued liabilities	34,717	12,834
Accrued compensation	(15,697)	(27,535)
Deferred rent, lease incentives, and others	–	(11,849)
Other assets	10,460	1,396
Subtotal	(1,273,335)	(1,158,002)
Interest paid	(10,084)	(6,061)
Net cash provided by (used in) operating activities	(1,283,419)	(1,164,063)
Cash flows from investing activities		
Interest received	13,307	2,943
Purchase of other financial assets	(295,390)	(581,342)
Proceeds from redemption upon maturity of other financial assets	3,020,081	755,331
Purchase of property, plant and equipment	–	(1,637)
Proceeds from collection of lease receivables	64,385	24,954
Proceeds from refund of leasehold and guarantee deposits	–	12,131
Net cash provided by (used in) investing activities	2,802,383	212,380
Cash flows from financing activities		
Proceeds from issuance of ordinary shares	243,874	607,891
Payment of lease liabilities	(72,060)	(43,696)
Net cash provided by (used in) financing activities	171,814	564,195
Effect of exchange rate changes on cash and cash equivalents	120,109	261,576
Net increase (decrease) in cash and cash equivalents	1,810,887	(125,912)
Cash and cash equivalents at beginning of period	2,533,786	3,977,312
Cash and cash equivalents at end of period	4,344,673	3,851,400

(5) Notes to condensed quarterly consolidated financial statements

Notes on going concern assumption

Not applicable.

Significant subsequent events

Not applicable.