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May 13, 2022

## Consolidated Financial Results for the Three Months Ended March 31, 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: May 13, 2022  
 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 three months ended March 31, 2022 (January 1, 2022 to March 31, 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	%
Three months ended								
March 31, 2022	–	–	(644)	–	(656)	–	(656)	–
March 31, 2021	–	–	(686)	–	(697)	–	(697)	–

	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
Three months ended						
March 31, 2022	(656)	–	(535)	–	(14.30)	(14.30)
March 31, 2021	(697)	–	(412)	–	(15.48)	(15.48)

#### (2) Consolidated financial position

	Total assets	Total shareholders' equity	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	%
March 31, 2022	4,270	3,633	3,633	85.1
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	–				
Fiscal year ending December 31, 2022 (Forecast)		0.00	–	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 March 31, 2022	45,861,688 shares
As of December 31, 2021	45,861,688 shares

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

As of March 31, 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 three months ended March 31, 2022	45,854,290 shares
For the three months ended March 31, 2021	44,996,576 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 Three Months ended March 31, 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.

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## 1. Qualitative Information Regarding Financial Results for the Three Months ended March 31, 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 three months ended March 31, 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 is currently ongoing across 29 sites in 11 countries worldwide. For the clinical study, the subjects are randomly assigned to a group receiving emixustat or a group receiving a placebo at a 2:1 ratio. Emixustat (10 mg) or the placebo is administered orally once a day for 24 months. The primary endpoint is to determine if emixustat reduces the rate of macular atrophy progression in subjects with Stargardt disease (juvenile macular degeneration) and the secondary endpoints include changes in visual function parameters, such as best-corrected visual acuity (BCVA) letter score and reading speed.

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. The enrollment of the last subject was completed in April 2020 (U.S. time) and database lock is expected to be completed in the nine months ending September 30, 2022 or thereafter if the study progresses according to schedule.

The phase 3 clinical study was selected for the Orphan Products Clinical Trials Grants Program by the U.S. Food and Drug Administration (FDA) in August 2020, and the Group is expected to receive the grants, of which the amount will be up to \$1.63 million, from this grants program over three years. The Group recorded a total of ¥57 million as other operating income for fiscal 2020, which was the first year of the grants, and recorded a total of ¥60 million in the previous fiscal year. It expects to record a similar amount in the current fiscal year, but no such income was recorded in the three months ended March 31, 2022.

Emixustat received orphan drug designation as a new drug candidate for treating Stargardt disease from the FDA in January 2017 and from the European Medicines Agency (EMA) in June 2019.

Prior to its ongoing phase 3 clinical study for Stargardt disease, the Group conducted a phase 2 clinical study for emixustat targeting proliferative diabetic retinopathy in the fiscal year ended December 31, 2017. Analysis of this clinical study suggests that emixustat may improve macular edema, but a phase 3 clinical study would be a large-scale clinical study requiring substantial research and development funding. As the Group believes it would be difficult to proceed independently, it is exploring the possibility of joint development with partner companies.

#### Medical devices

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 2020, the Group has continued to improve its functions and software, and is exploring the possibility of joint development and commercialization with partner companies. In the three months ended March 31, 2022, a prospective study was commenced by KAGOSHIMA SONODA Eye Clinic & Plastic Surgery.

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 2020. Discussions regarding the details of Phase 2 of this project continue, but the timing of its commencement has not been decided.

With regard to Kubota Glass™, 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. The Group has completed an initial prototype. In the previous fiscal year, the Group received medical

device registration approval in Taiwan, and received “ISO 13485:2016” certification for the design and development of ophthalmic medical devices. The Group is proceeding with product development toward commercialization and implementing design improvement for preparation for production and sales, as well as setting up a branch office in Taiwan, while continuing clinical studies aimed at obtaining more evidence, and other activities.

#### Research and development expenses

Research and development expenses for the three months ended March 31, 2022, was ¥499 million, a decrease of ¥8 million, or 1.6%, year on year. This was mainly due to a decrease in development expenses for the remote retinal monitoring device PBOS and gene therapy, despite an increase in development expenses for wearable myopia control devices.

(Unit: Thousands of yen or %)

	Three months ended March 31, 2021	Three months ended March 31, 2022	Increase (Decrease)	Change (%)
Research and development expenses	506,659	498,661	(7,998)	(1.6)

#### General and administrative expenses

General and administrative expenses for the three months ended March 31, 2022, was ¥146 million, a decrease of ¥33 million, or 18.6%, 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 %)

	Three months ended March 31, 2021	Three months ended March 31, 2022	Increase (Decrease)	Change (%)
General and administrative expenses	179,033	145,817	(33,216)	(18.6)

## **(2) Explanation of financial position**

#### Current assets

Current assets as of the end of the first quarter of the current fiscal year was ¥4,063 million, a decrease of ¥562 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 first quarter of the current fiscal year was ¥207 million, a decrease of ¥1 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 first quarter of the current fiscal year was ¥502 million, a decrease of ¥40 million from the end of the previous fiscal year. This was mainly due to decreases in trade payables and accrued compensation, despite an increase in accrued liabilities.

#### Non-current liabilities

Non-current liabilities as of the end of the first quarter of the current fiscal year was ¥135 million, a decrease of ¥3 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 first quarter of the current fiscal year was ¥3,633 million, a decrease of ¥520 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 March 31, 2022
(Thousands of yen)		
<b>Assets</b>		
Current assets		
Cash and cash equivalents	3,977,312	3,221,182
Other financial assets	438,582	721,233
Other current assets	209,378	120,516
Total current assets	4,625,272	4,062,931
Non-current assets		
Property, plant and equipment	192,427	191,118
Other non-current assets	14,865	15,619
Total non-current assets	207,292	206,737
Total assets	4,832,564	4,269,668
<b>Liabilities and equity</b>		
Liabilities		
Current liabilities		
Trade payables	75,085	46,449
Accrued liabilities	323,220	372,968
Accrued compensation	70,039	39,704
Deferred rent, lease incentives, and others	11,697	-
Lease liabilities	62,312	43,136
Total current liabilities	542,353	502,257
Non-current liabilities		
Lease liabilities	137,290	134,599
Total non-current liabilities	137,290	134,599
Total liabilities	679,643	636,856
Shareholders' equity		
Share capital	1,308,902	1,308,902
Capital surplus	26,755,419	26,770,609
Retained earnings (loss)	(22,164,748)	(22,820,269)
Other components of equity	(1,746,652)	(1,626,430)
Total equity attributable to owners of parent	4,152,921	3,632,812
Total shareholders' equity	4,152,921	3,632,812
Total liabilities and shareholders' equity	4,832,564	4,269,668

**(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**

Three months ended March 31, 2021 and 2022

	(Thousands of yen)	
	Three months ended March 31, 2021	Three months ended March 31, 2022
Business expenses		
Research and development expenses	506,659	498,661
General and administrative expenses	179,033	145,817
Total business expenses	685,692	644,478
Operating loss	(685,692)	(644,478)
Other income and expenses		
Finance income	5,205	1,004
Finance costs	(5,383)	(3,162)
Other income (expenses)	(10,684)	(8,885)
Total other income and expenses	(10,862)	(11,043)
Loss before tax	(696,554)	(655,521)
Net loss	(696,554)	(655,521)
Loss attributable to		
Owners of parent	(696,554)	(655,521)
Net loss per share		
Basic loss per share (Yen)	(15.48)	(14.30)
Diluted loss per share (Yen)	(15.48)	(14.30)

**Condensed quarterly consolidated statements of comprehensive income**

Three months ended March 31, 2021 and 2022

	(Thousands of yen)	
	Three months ended March 31, 2021	Three months ended March 31, 2022
Net loss	(696,554)	(655,521)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	284,474	120,222
Total other comprehensive income	284,474	120,222
Comprehensive income	(412,080)	(535,299)
Comprehensive income attributable to		
Owners of parent	(412,080)	(535,299)

**(3) Condensed quarterly consolidated statements of changes in equity**

Three months ended March 31, 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			(696,554)		(696,554)	(696,554)
Exchange differences on translation of foreign operations				284,474	284,474	284,474
Comprehensive income	-	-	(696,554)	284,474	(412,080)	(412,080)
Share-based compensation expense		30,032			30,032	30,032
Issuance of new shares	96,488	96,488			192,976	192,976
Issuance cost of new shares		(903)			(903)	(903)
Total equity transactions with owners	96,488	125,617	-	-	222,105	222,105
Balance as of March 31, 2021	1,245,138	26,649,038	(20,244,851)	(1,846,221)	5,803,104	5,803,104

Three months ended March 31, 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			(655,521)		(655,521)	(655,521)
Exchange differences on translation of foreign operations				120,222	120,222	120,222
Comprehensive income	-	-	(655,521)	120,222	(535,299)	(535,299)
Share-based compensation expense		15,190			15,190	15,190
Total equity transactions with owners	-	15,190	-	-	15,190	15,190
Balance as of March 31, 2022	1,308,902	26,770,609	(22,820,269)	(1,626,430)	3,632,812	3,632,812

**(4) Condensed quarterly consolidated statements of cash flows**

	(Thousands of yen)	
	Three months ended March 31, 2021	Three months ended March 31, 2022
Cash flows from operating activities		
Net loss	(696,554)	(655,521)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	14,408	13,520
Share-based compensation expense	30,032	15,190
Amortization of premium or discount on securities	2,159	(537)
Finance income	(5,205)	(1,004)
Finance costs	5,383	3,162
Change in operating assets and liabilities		
Other current assets	(11,007)	97,321
Trade payables	12,673	(31,842)
Accrued liabilities	48,732	27,644
Accrued compensation	(28,242)	(33,151)
Deferred rent, lease incentives, and others	-	(11,849)
Other assets	10,017	188
Subtotal	(617,604)	(576,879)
Interest paid	(5,263)	(3,108)
Net cash provided by (used in) operating activities	(622,867)	(579,987)
Cash flows from investing activities		
Interest received	5,737	980
Purchase of other financial assets	-	(581,342)
Proceeds from redemption upon maturity of other financial assets	1,847,942	314,593
Purchase of property, plant and equipment	-	(248)
Proceeds from collection of lease receivables	31,113	24,954
Net cash provided by (used in) investing activities	1,884,792	(241,063)
Cash flows from financing activities		
Proceeds from issuance of ordinary shares	194,421	-
Payment of lease liabilities	(35,135)	(32,994)
Net cash provided by (used in) financing activities	159,286	(32,994)
Effect of exchange rate changes on cash and cash equivalents	121,061	97,914
Net increase (decrease) in cash and cash equivalents	1,542,272	(756,130)
Cash and cash equivalents at beginning of period	2,533,786	3,977,312
Cash and cash equivalents at end of period	4,076,058	3,221,182

**(5) Notes to condensed quarterly consolidated financial statements**

**Notes on going concern assumption**

Not applicable.

**Significant subsequent events**

*Grant of share options*

The Company resolved, at its 7th Ordinary General Meeting of Shareholders (for the fiscal year 2021) held on April 22, 2022, to delegate to the Board of Directors of the Company the authority to determine the offering terms for share acquisition rights issued as share options without contribution, pursuant to the provisions of Article 236, Article 238 and Article 239 of the Companies Act.

The details are as follows:

- (1) Persons eligible for allotment of share acquisition rights  
Directors (including outside directors), executive officers, employees and consultants of the Company, and directors (including outside directors), employees and consultants of subsidiaries of the Company
- (2) Class and number of shares underlying share acquisition rights  
The upper limit shall be 1,800,000 ordinary shares of the Company.  
However, in the event that the Company implements a share split of ordinary shares of the Company (including the allotment of ordinary shares of the Company without contribution; the same shall apply to the description of the share split hereinafter) or a share consolidation of the shares on or after the date when the Board of Directors of the Company resolves to offer share acquisition rights (the “Resolution Date”), the number of granted shares shall be adjusted using the following formula and any fraction less than one share arising from such adjustment shall be discarded.  
$$\text{Number of granted shares after adjustment} = \text{Number of granted shares before adjustment} \times \text{Ratio of share split or share consolidation}$$
- (3) Total number of share acquisition rights to be issued  
The upper limit shall be 18,000 units.
- (4) Issue price of share acquisition rights  
No cash payment in exchange for the share acquisition rights shall be required.
- (5) Value of property to be contributed upon exercise of share acquisition rights  
The amount of property to be contributed upon exercise of each of the share acquisition rights shall be the amount to be paid per share that may be issued upon exercise of the share acquisition rights (the “Exercise Price”) multiplied by the number of granted shares.  
The Exercise Price shall be either the average value (rounding up any fraction less than ¥1) of the closing price of ordinary shares of the Company in regular trading at the Tokyo Stock Exchange (the “Closing Price”) for each day (excluding days on which no trades are executed) of the month preceding the month that includes the date of allotment of share acquisition rights (the “Allotment Date”) or the Closing Price on the Allotment Date (if there is no Closing Price, the Closing Price of the most recent date is used), whichever is higher.
- (6) Exercise period of share acquisition rights  
This shall be the period from the Allotment Date to the date on which 10 years elapse since the Resolution Date of granting the share acquisition rights.
- (7) Exercise conditions of share acquisition rights  
The exercise conditions of share acquisition rights shall be as set forth in (9), below, of the Share Acquisition Rights Allotment Agreement.
- (8) Matters concerning the amount of increase in share capital and legal capital surplus resulting from issuance of shares upon exercise of share acquisition rights
  - (i) The amount of increase in share capital resulting from the issuance of shares upon exercise of the share acquisition rights shall be one-half of the maximum amount of increase in share capital as calculated pursuant to provisions of Article 17 of the Regulation on Corporate Accounting. Any fraction less than ¥1 arising from such calculation shall be rounded up to the nearest yen.

- (ii) The amount of increase in legal capital surplus resulting from the issuance of shares upon exercise of share acquisition rights shall be the maximum amount of increase in share capital as provided in (i) above less the amount of increase in share capital as determined in (i) above.
- (9) Other matters
- The allotment of share acquisition rights shall be based on and executed in accordance with a Share Acquisition Rights Allotment Agreement that sets forth the conditions that the Board of Directors deems necessary to achieve the issuance of the above-mentioned share acquisition rights, and such agreement shall be entered into by the Company and persons eligible for allotment of share acquisition rights.