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May 13, 2021

Consolidated Financial Results for the Three Months Ended March 31, 2021 (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, 2021
 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, 2021 (January 1, 2021 to March 31, 2021)

(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, 2021	0	–	(686)	–	(697)	–	(697)	–
March 31, 2020	0	–	(741)	–	(713)	–	(713)	–

	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, 2021	(697)	–	(412)	–	(15.48)	(15.48)
March 31, 2020	(713)	–	(759)	–	(16.87)	(16.87)

(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	%
March 31, 2021	6,549	5,803	5,803	88.6
December 31, 2020	6,692	5,993	5,993	89.6

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, 2020	Yen –	Yen 0.00	Yen –	Yen 0.00	Yen 0.00
Fiscal year ending December 31, 2021	–				
Fiscal year ending December 31, 2021 (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, 2021 (January 1, 2021 to December 31, 2021)

(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	10	(73.5)	(2,900)	–	(2,800)	–	(2,800)	–

	Profit attributable to owners of parent		Basic earnings per share
	Millions of yen	%	Yen
Full year	(2,800)	–	(62.84)

(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, 2021	45,316,688 shares
As of December 31, 2020	44,558,588 shares

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

As of March 31, 2021	70 shares
As of December 31, 2020	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, 2021	44,996,576 shares
For the three months ended March 31, 2020	42,295,790 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, 2021, (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, 2021

(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, 2021, 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”), we 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 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 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).

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. The total amount of grants to be provided from this grants program will be up to \$1.63 million (approximately ¥170 million) over three years. The Group recorded a total of ¥57 million as other operating income for the previous fiscal year, which was the first year of the grants. 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, 2021.

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 our 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 July 2020, we have continued to improve its functions and are 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 is also working with the National Aeronautics and Space Administration (NASA) to develop a compact optical coherence tomography (OCT) device that can be carried on a 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 is also developing wearable myopia control devices aimed at treating and controlling the progression of myopia utilizing Kubota Glass technology, the Group’s original active stimulation technology. In 2020, a proof-of-concept (POC) clinical study using a desktop device and 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 completed an initial prototype in December 2020, and is currently continuing product development toward early commercialization, clinical studies aimed at obtaining more evidence and other activities.

Gene therapy

In gene therapy, we continued the preclinical study for improving the effect of promoters and capsids as well as altering transgenes for retinitis pigmentosa, which is a hereditary retinal disease.

Research and development expenses

Research and development expenses for the three months ended March 31, 2021, was ¥507 million, a decrease of ¥74 million, or 12.8%, year on year. This was mainly due to decreases in research and development expenses for emixustat, for which enrollment of subject has been completed, and in development expenses for the remote retinal monitoring device PBOS, despite an increase in development expenses for wearable myopia control devices.

(Unit: Thousands of yen or %)

	Three months ended March 31, 2020	Three months ended March 31, 2021	Increase (Decrease)	Change (%)
Research and development expenses	580,952	506,659	(74,293)	(12.8)

General and administrative expenses

General and administrative expenses for the three months ended March 31, 2021, was ¥179 million, an increase of ¥19 million, or 12.0%, year on year. This was mainly due to an increase in patent-related expenses following progress in the various projects.

(Unit: Thousands of yen or %)

	Three months ended March 31, 2020	Three months ended March 31, 2021	Increase (Decrease)	Change (%)
General and administrative expenses	159,799	179,033	19,234	12.0

(2) Explanation of financial position

Current assets

Current assets as of the end of the first quarter of the current fiscal year was ¥6,303 million, a decrease of ¥114 million from the end of the previous fiscal year. This was mainly due to a decrease in other financial assets.

Non-current assets

Non-current assets as of the end of the first quarter of the current fiscal year was ¥245 million, a decrease of ¥30 million from the end of the previous fiscal year. This was mainly due to a decrease in other financial assets.

Current liabilities

Current liabilities as of the end of the first quarter of the current fiscal year was ¥570 million, an increase of ¥63 million from the end of the previous fiscal year. This was mainly due to 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 ¥175 million, a decrease of ¥17 million from the end of the previous fiscal year. This was mainly 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 ¥5,803 million, a decrease of ¥190 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, 2021, that the Group announced on February 12, 2021, the analysis was predicated on the spread of COVID-19 and other factors, and no changes have been made to them at this point.

Furthermore, although the Group believes that the effects of the spread of COVID-19 and other factors on business performance will be insignificant, we 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, 2020	As of March 31, 2021
(Thousands of yen)		
Assets		
Current assets		
Cash and cash equivalents	2,533,786	4,076,058
Other financial assets	3,782,856	2,109,049
Other current assets	100,381	118,200
Total current assets	6,417,023	6,303,307
Non-current assets		
Property, plant and equipment	220,228	220,941
Other financial assets	22,167	-
Other non-current assets	32,518	24,342
Total non-current assets	274,913	245,283
Total assets	6,691,936	6,548,590
Liabilities and equity		
Liabilities		
Current liabilities		
Trade payables	68,612	86,603
Accrued liabilities	226,197	292,754
Accrued compensation	72,058	47,637
Lease liabilities	139,784	143,053
Total current liabilities	506,651	570,047
Non-current liabilities		
Long-term liabilities	12,595	13,473
Lease liabilities	179,611	161,966
Total non-current liabilities	192,206	175,439
Total liabilities	698,857	745,486
Shareholders' equity		
Share capital	1,148,650	1,245,138
Capital surplus	26,523,421	26,649,038
Retained earnings (loss)	(19,548,297)	(20,244,851)
Other components of equity	(2,130,695)	(1,846,221)
Total equity attributable to owners of parent	5,993,079	5,803,104
Total shareholders' equity	5,993,079	5,803,104
Total liabilities and shareholders' equity	6,691,936	6,548,590

(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, 2020 and 2021

	(Thousands of yen)	
	Three months ended March 31, 2020	Three months ended March 31, 2021
Business expenses		
Research and development expenses	580,952	506,659
General and administrative expenses	159,799	179,033
Total business expenses	740,751	685,692
Operating loss	(740,751)	(685,692)
Other income and expenses		
Finance income	34,034	5,205
Finance costs	(4,383)	(5,383)
Other income (expenses)	(2,226)	(10,684)
Total other income and expenses	27,425	(10,862)
Loss before tax	(713,326)	(696,554)
Net loss	(713,326)	(696,554)
Loss attributable to Owners of parent	(713,326)	(696,554)
Net loss per share		
Basic loss per share (Yen)	(16.87)	(15.48)
Diluted loss per share (Yen)	(16.87)	(15.48)

Condensed quarterly consolidated statements of comprehensive income

	(Thousands of yen)	
	Three months ended March 31, 2020	Three months ended March 31, 2021
Net loss	(713,326)	(696,554)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(45,729)	284,474
Total other comprehensive income	(45,729)	284,474
Comprehensive income	(759,055)	(412,080)
Comprehensive income attributable to Owners of parent	(759,055)	(412,080)

(3) Condensed quarterly consolidated statements of changes in equity

Three months ended March 31, 2020

(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, 2020	842,595	26,160,540	(17,110,873)	(1,815,180)	8,077,082	8,077,082
Net loss			(713,326)		(713,326)	(713,326)
Exchange differences on translation of foreign operations				(45,729)	(45,729)	(45,729)
Comprehensive income	–	–	(713,326)	(45,729)	(759,055)	(759,055)
Share-based compensation expense		13,832			13,832	13,832
Total equity transactions with owners	–	13,832	–	–	13,832	13,832
Balance as of March 31, 2020	842,595	26,174,372	(17,824,199)	(1,860,909)	7,331,859	7,331,859

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

(4) Condensed quarterly consolidated statements of cash flows

	(Thousands of yen)	
	Three months ended March 31, 2020	Three months ended March 31, 2021
Cash flows from operating activities		
Net loss	(713,326)	(696,554)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	10,944	14,408
Share-based compensation expense	13,832	30,032
Amortization of premium or discount on securities	(4,828)	2,159
Finance income	(34,034)	(5,205)
Finance costs	4,383	5,383
Change in operating assets and liabilities		
Other current assets	17,999	(11,007)
Trade payables	8,579	12,673
Accrued liabilities	56,796	48,732
Accrued compensation	(18,218)	(28,242)
Lease liabilities	(2,178)	-
Other assets	498	10,017
Subtotal	(659,553)	(617,604)
Interest paid	(4,443)	(5,263)
Net cash provided by (used in) operating activities	(663,996)	(622,867)
Cash flows from investing activities		
Interest received	38,526	5,737
Purchase of other financial assets	(485,447)	-
Proceeds from redemption upon maturity of other financial assets	1,689,601	1,847,942
Proceeds from collection of lease receivables	18,525	31,113
Net cash provided by (used in) investing activities	1,261,205	1,884,792
Cash flows from financing activities		
Proceeds from issuance of ordinary shares	-	194,421
Payment of lease liabilities	(41,955)	(35,135)
Net cash provided by (used in) financing activities	(41,955)	159,286
Effect of exchange rate changes on cash and cash equivalents	(27,807)	121,061
Net increase in cash and cash equivalents	527,447	1,542,272
Cash and cash equivalents at beginning of period	4,192,367	2,533,786
Cash and cash equivalents at end of period	4,719,814	4,076,058

(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 6th Ordinary General Meeting of Shareholders (for the fiscal year 2020) held on April 23, 2021, 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 1,200,000 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 12,000 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 (discarding values of 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 date of the resolution 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.