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November 12, 2021

Consolidated Financial Results for the Nine Months Ended September 30, 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: November 12, 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 nine months ended September 30, 2021 (January 1, 2021 to September 30, 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	%
Nine months ended								
September 30, 2021	–	–	(1,908)	–	(1,931)	–	(1,931)	–
September 30, 2020	38	–	(1,916)	–	(1,872)	–	(1,872)	–

	Profit attributable to owners of parent		Total comprehensive income		Basic earnings per share	Diluted earnings per share
	Millions of yen	%	Millions of yen	%	Yen	Yen
Nine months ended						
September 30, 2021	(1,931)	–	(1,622)	–	(42.50)	(42.50)
September 30, 2020	(1,872)	–	(2,082)	–	(44.11)	(44.11)

(2) Consolidated financial position

	Total assets	Total shareholders' equity	Equity attributable to owners of parent	Ratio of equity attributable to owners of parent
	Millions of yen	Millions of yen	Millions of yen	%
As of				
September 30, 2021	5,378	4,747	4,747	88.3
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	–	0.00	–		
Fiscal year ending December 31, 2021 (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, 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 September 30, 2021	45,861,688 shares
As of December 31, 2020	44,558,588 shares

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

As of September 30, 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 nine months ended September 30, 2021	45,429,339 shares
For the nine months ended September 30, 2020	42,436,807 shares

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

- * Proper use of earnings forecasts, and other special items

The earnings forecasts and other forward-looking statements contained in these materials are based on information currently available to Kubota Pharmaceutical Holdings Co., Ltd. (the "Company") and on certain assumptions deemed to be reasonable by the Company. Actual business performance and other results may differ substantially due to various factors. Please refer to "1. Qualitative Information Regarding Financial Results for the Nine Months ended September 30, 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 Nine Months ended September 30, 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 nine months ended September 30, 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 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 second half of 2022 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 total amount will be up to \$1.63 million (approximately ¥170 million), from this grants program 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. Similarly, in the current fiscal year, the Group recorded ¥60 million as other operating income for the nine months ended September 30, 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 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 also worked 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.

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. In December 2020, the Group has completed an initial prototype. In the current fiscal year, the Group disclosed that it received “ISO 13485:2016” certification in October 2021 as a company that designs

and develops ophthalmic medical devices, in addition to receiving the medical device registration approval in Taiwan. The Group is proceeding with product development toward early commercialization and preparation for production and sales, while continuing clinical studies aimed at obtaining more evidence and other activities.

Gene therapy

In gene therapy, we have continued the pre-clinical study for retinitis pigmentosa, a hereditary retinal disease, but as the Group reconsiders its research and development priorities, the future cash investments in this program will be put on hold to allocate more resources into the projects that are in their later development stages.

Research and development expenses

Research and development expenses for the nine months ended September 30, 2021, was ¥1,500 million, a decrease of ¥29 million, or 1.9%, 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 %)

	Nine months ended September 30, 2020	Nine months ended September 30, 2021	Increase (Decrease)	Change (%)
Research and development expenses	1,529,364	1,500,304	(29,060)	(1.9)

General and administrative expenses

General and administrative expenses for the nine months ended September 30, 2021, was ¥468 million, a decrease of ¥1 million, or 0.2%, year on year. This was mainly due to a decrease in other general and administrative expenses associated with the cost-saving measures, despite increases in patent-related expenses and business development expenses following progress in the various projects.

(Unit: Thousands of yen or %)

	Nine months ended September 30, 2020	Nine months ended September 30, 2021	Increase (Decrease)	Change (%)
General and administrative expenses	468,886	467,916	(970)	(0.2)

(2) Explanation of financial position

Current assets

Current assets as of the end of the third quarter of the current fiscal year was ¥5,152 million, a decrease of ¥1,265 million from the end of the previous fiscal year. This was mainly due to a decrease in other financial assets as they reached maturity.

Non-current assets

Non-current assets as of the end of the third quarter of the current fiscal year was ¥226 million, a decrease of ¥49 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 third quarter of the current fiscal year was ¥485 million, a decrease of ¥21 million from the end of the previous fiscal year. This was mainly due to a decrease in lease liabilities.

Non-current liabilities

Non-current liabilities as of the end of the third quarter of the current fiscal year was ¥146 million, a decrease of ¥46 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 third quarter of the current fiscal year was ¥4,747 million, a decrease of ¥1,246 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.

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.

Moving forward, status updates on our gene therapy pre-clinical research will be made upon appropriate progress, as is done for other projects in early research stages, instead of including information in the Group's pipeline chart.

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 September 30, 2021
(Thousands of yen)		
Assets		
Current assets		
Cash and cash equivalents	2,533,786	4,498,138
Other financial assets	3,782,856	462,053
Other current assets	100,381	192,049
Total current assets	6,417,023	5,152,240
Non-current assets		
Property, plant and equipment	220,228	202,046
Other financial assets	22,167	-
Other non-current assets	32,518	23,888
Total non-current assets	274,913	225,934
Total assets	6,691,936	5,378,174
Liabilities and equity		
Liabilities		
Current liabilities		
Trade payables	68,612	85,962
Accrued liabilities	226,197	240,093
Accrued compensation	72,058	59,372
Lease liabilities	139,784	88,409
Other current liabilities	-	11,382
Total current liabilities	506,651	485,218
Non-current liabilities		
Long-term liabilities	12,595	2,238
Lease liabilities	179,611	143,876
Total non-current liabilities	192,206	146,114
Total liabilities	698,857	631,332
Shareholders' equity		
Share capital	1,148,650	1,308,902
Capital surplus	26,523,421	26,739,035
Retained earnings (loss)	(19,548,297)	(21,478,869)
Other components of equity	(2,130,695)	(1,822,226)
Total equity attributable to owners of parent	5,993,079	4,746,842
Total shareholders' equity	5,993,079	4,746,842
Total liabilities and shareholders' equity	6,691,936	5,378,174

(2) Condensed quarterly consolidated statements of profit or loss and condensed quarterly consolidated statements of comprehensive income

Condensed quarterly consolidated statements of profit or loss

Nine months ended September 30, 2020 and 2021

	(Thousands of yen)	
	Nine months ended September 30, 2020	Nine months ended September 30, 2021
Revenue	37,786	-
Business expenses		
Research and development expenses	1,529,364	1,500,304
General and administrative expenses	468,886	467,916
Total business expenses	<u>1,998,250</u>	<u>1,968,220</u>
Other operating income	43,994	59,874
Operating loss	<u>(1,916,470)</u>	<u>(1,908,346)</u>
Other income and expenses		
Finance income	60,718	10,086
Finance costs	(11,721)	(14,455)
Other income (expenses)	(4,379)	(17,857)
Total other income and expenses	<u>44,618</u>	<u>(22,226)</u>
Loss before tax	<u>(1,871,852)</u>	<u>(1,930,572)</u>
Net loss	<u>(1,871,852)</u>	<u>(1,930,572)</u>
Loss attributable to Owners of parent	(1,871,852)	(1,930,572)
Net loss per share		
Basic loss per share (Yen)	(44.11)	(42.50)
Diluted loss per share (Yen)	(44.11)	(42.50)

Condensed quarterly consolidated statements of comprehensive income

Nine months ended September 30, 2020 and 2021

	(Thousands of yen)	
	Nine months ended September 30, 2020	Nine months ended September 30, 2021
Net loss	(1,871,852)	(1,930,572)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(209,966)	308,469
Total other comprehensive income	<u>(209,966)</u>	<u>308,469</u>
Comprehensive income	<u>(2,081,818)</u>	<u>(1,622,103)</u>
Comprehensive income attributable to Owners of parent	(2,081,818)	(1,622,103)

(3) Condensed quarterly consolidated statements of changes in equity

Nine months ended September 30, 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			(1,871,852)		(1,871,852)	(1,871,852)
Exchange differences on translation of foreign operations				(209,966)	(209,966)	(209,966)
Comprehensive income	–	–	(1,871,852)	(209,966)	(2,081,818)	(2,081,818)
Share-based compensation expense		42,768			42,768	42,768
Issuance of new shares	130,714	130,714			261,428	261,428
Issuance cost of new shares		(8,712)			(8,712)	(8,712)
Total equity transactions with owners	130,714	164,770	–	–	295,484	295,484
Balance as of September 30, 2020	973,309	26,325,310	(18,982,725)	(2,025,146)	6,290,748	6,290,748

Nine months ended September 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			(1,930,572)		(1,930,572)	(1,930,572)
Exchange differences on translation of foreign operations				308,469	308,469	308,469
Comprehensive income	–	–	(1,930,572)	308,469	(1,622,103)	(1,622,103)
Share-based compensation expense		58,376			58,376	58,376
Issuance of new shares	160,252	160,252			320,504	320,504
Issuance cost of new shares		(3,014)			(3,014)	(3,014)
Total equity transactions with owners	160,252	215,614	–	–	375,866	375,866
Balance as of September 30, 2021	1,308,902	26,739,035	(21,478,869)	(1,822,226)	4,746,842	4,746,842

(4) Condensed quarterly consolidated statements of cash flows

	(Thousands of yen)	
	Nine months ended September 30, 2020	Nine months ended September 30, 2021
Cash flows from operating activities		
Net loss	(1,871,852)	(1,930,572)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	32,910	43,819
Share-based compensation expense	42,768	58,376
Amortization of premium or discount on securities	(6,374)	2,336
Finance income	(60,718)	(10,086)
Finance costs	11,721	14,455
Change in operating assets and liabilities		
Other current assets	75,246	(88,596)
Other current liabilities	(37,127)	-
Trade payables	(42,204)	11,356
Accrued liabilities	127,129	(6,162)
Accrued compensation	11,829	(17,274)
Lease liabilities	(2,178)	-
Other assets	(11,861)	10,723
Subtotal	(1,730,711)	(1,911,625)
Interest paid	(11,797)	(14,308)
Net cash provided by (used in) operating activities	(1,742,508)	(1,925,933)
Cash flows from investing activities		
Interest received	70,714	16,658
Purchase of other financial assets	(3,724,974)	(394,378)
Proceeds from redemption upon maturity of other financial assets	3,777,550	3,813,038
Purchase of property, plant and equipment	(18,074)	(8,272)
Proceeds from collection of lease receivables	78,347	98,718
Proceeds from refund of leasehold and guarantee deposits	11,488	-
Net cash provided by (used in) investing activities	195,051	3,525,764
Cash flows from financing activities		
Proceeds from issuance of ordinary shares	248,177	319,898
Proceeds from issuance of share acquisition rights	4,590	-
Payment of lease liabilities	(107,002)	(109,790)
Net cash provided by (used in) financing activities	145,765	210,108
Effect of exchange rate changes on cash and cash equivalents	(147,319)	154,413
Net increase (decrease) in cash and cash equivalents	(1,549,011)	1,964,352
Cash and cash equivalents at beginning of period	4,192,367	2,533,786
Cash and cash equivalents at end of period	2,643,356	4,498,138

(5) Notes to condensed quarterly consolidated financial statements

Notes on going concern assumption

Not applicable.

Significant subsequent events

Not applicable.