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November 11, 2022

Consolidated Financial Results for the Nine Months Ended September 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: November 11, 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 nine months ended September 30, 2022 (January 1, 2022 to September 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 | % |
| Nine months ended | | | | | | | | |
| September 30, 2022 | 3 | – | (1,653) | – | (1,681) | – | (1,681) | – |
| September 30, 2021 | – | – | (1,908) | – | (1,931) | – | (1,931) | – |

| | 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, 2022 | (1,681) | – | (1,293) | – | (35.20) | (35.20) |
| September 30, 2021 | (1,931) | – | (1,622) | – | (42.50) | (42.50) |

(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, 2022 | 4,706 | 4,083 | 4,083 | 86.8 |
| 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 | 7 | – | (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: Yes

*** 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, 2022 | 52,109,988 shares |
| As of December 31, 2021 | 45,861,688 shares |

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

| | |
|--------------------------|-----------|
| As of September 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 nine months ended September 30, 2022 | 47,752,421 shares |
| For the nine months ended September 30, 2021 | 45,429,339 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, 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 Nine Months ended September 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 nine months ended September 30, 2022, the outlook remains uncertain. Although the impact of the novel coronavirus disease (COVID-19) appeared to ease, inflationary pressure increased due to background factors such as supply constraints and high resource prices caused by the prolonged conflict in Ukraine, while a prolonged depreciation of the yen is also expected, mainly due to the widening divergence between Japanese and US interest rates.

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

Medical devices

Wearable myopia control device (Kubota Glass™)

Currently under development by the Group, Kubota Glass™ technology 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 2020, the Company’s US subsidiary, Kubota Vision Inc. (“Kubota Vision”), conducted a clinical study of 12 subjects with a prototype desktop device that used Kubota Glass technology to verify the impact on the axial length of the eye. The study demonstrated that axial length in the tested eye decreased compared to the control eye. Next, Kubota Vision completed verification that a similar effect was demonstrated with a wearable device using the same technology in 25 subjects aged 18 to 35 with myopia. Usually, the axial length increases or stops growing with age. The shortening of the axial length due to artificial light compared to the control eye is a world first. The Group envisions applications of this technology in smart glasses and smart contact lenses for a world without eyeglasses.

In December 2020, the initial prototype was completed, and 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 2022, the Group completed the registration of medical devices with the U.S. FDA and began sales at some ophthalmic clinics in the U.S. and Japan 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 continue with its 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.

Home-based and remote medical monitoring device

The Group is developing the Patient Based Ophthalmology Suite (PBOS) for a miniature optical coherence tomography (OCT) device. It is a miniature 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. It is a testing device that enables patients diagnosed and treated for wet age-related macular degeneration (AMD) and diabetic macular edema (DME) to measure the state of their retina themselves at home. By establishing a system that enables physicians to remotely examine the progression of symptoms such as changes in retinal anatomy and vision via the internet, the Group aims to help individual patients receive optimal ophthalmological treatment to maintain and improve their vision. Since the initial prototype was completed in 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).

Small molecule compounds

With regard to emixustat hydrochloride (“emixustat”), the Group completed the enrollment of the first subject of the phase 3 clinical study for Stargardt disease on November 7, 2018 (U.S. time), and the

study was ongoing globally. Although the initial target for the study was 162 subjects, the Group increased the number of enrolled subjects in light of the impact of the spread of COVID-19 and other factors, and finally completed the enrollment of 194 subjects. 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 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 of further subsequent analysis, when comparing the subject group with a smaller atrophic lesion area at the baseline time against the group that received the placebo, it was demonstrated that the progression of the atrophic lesion was significantly slowed in the group receiving emixustat, and a subgroup analysis was conducted to verify this. A multi-factor analysis was performed on the subgroup of subjects with smaller lesions at baseline, controlling for the baseline factors identified in univariate and multi-factor analyses to affect lesion progression in this subgroup. The result of this analysis found that the progression rate of macular atrophy in the group receiving emixustat was slowed by 40.8% at Month 24 compared with the placebo group (p=0.0206, emixustat receiving group n=34, placebo group n=21).

Given the above result, the Group plans to continue its activities, such as searching for co-development partners, while reconsidering its future plans for emixustat.

For the nine months ended September 30, 2022, revenue was ¥3 million, and cost of sales was ¥3 million. Research and development expenses, selling, general and administrative expenses are as follows:

Research and development expenses

Research and development expenses for the nine months ended September 30, 2022, was ¥1,306 million, a decrease of ¥195 million, or 13.0%, year on year. This was mainly due to a decrease in development expenses for wearable myopia control devices and the remote retinal monitoring device PBOS.

(Unit: Thousands of yen or %)

| | Nine months ended September 30, 2021 | Nine months ended September 30, 2022 | Increase (Decrease) | Change (%) |
|-----------------------------------|---|---|---------------------|------------|
| Research and development expenses | 1,500,304 | 1,305,802 | (194,502) | (13.0) |

Selling, general and administrative expenses

Selling, general and administrative expenses for the nine months ended September 30, 2022, was ¥421 million, a decrease of ¥47 million, or 9.9%, year on year. This was mainly due to year-on-year decreases in patent-related expenses and other general and administrative expenses associated with the cost-saving measures.

(Unit: Thousands of yen or %)

| | Nine months ended September 30, 2021 | Nine months ended September 30, 2022 | Increase (Decrease) | Change (%) |
|--|---|---|---------------------|------------|
| Selling, general and administrative expenses | 467,916 | 421,391 | (46,525) | (9.9) |

(2) Explanation of financial position

Current assets

Current assets as of the end of the third quarter of the current fiscal year was ¥4,500 million, a decrease of ¥125 million from the end of the previous fiscal year. This was mainly due to a decrease in other financial assets despite an increase in cash and cash equivalents.

Non-current assets

Non-current assets as of the end of the third quarter of the current fiscal year was ¥205 million, a decrease of ¥2 million from the end of the previous fiscal year. This was mainly due to a decrease in other non-current assets.

Current liabilities

Current liabilities as of the end of the third quarter of the current fiscal year was ¥504 million, a decrease of ¥38 million from the end of the previous fiscal year. This was mainly due to decreases in accrued compensation and lease liabilities.

Non-current liabilities

Non-current liabilities as of the end of the third quarter of the current fiscal year was ¥118 million, a decrease of ¥19 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 third quarter of the current fiscal year was ¥4,083 million, a decrease of ¥70 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 consolidated earnings forecasts, revenue was recognized during the third quarter of the current fiscal year due to the start of sales as a soft launch of wearable myopia control devices (Kubota Glass™), and with sales to continue in the fourth quarter of the current fiscal year, the consolidated earnings forecast for the fiscal year ending December 31, 2022 announced on February 14, 2022 has been revised.

For details, please refer to “Notice Concerning Revision of Earnings Forecasts” announced today (November 11, 2022).

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 September 30, 2022 |
|--|----------------------------|-----------------------------|
| (Thousands of yen) | | |
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | 3,977,312 | 4,372,646 |
| Trade receivables | – | 3,713 |
| Inventories | – | 10,426 |
| Other financial assets | 438,582 | – |
| Other current assets | 209,378 | 113,619 |
| Total current assets | 4,625,272 | 4,500,404 |
| Non-current assets | | |
| Property, plant and equipment | 192,427 | 195,751 |
| Other non-current assets | 14,865 | 9,456 |
| Total non-current assets | 207,292 | 205,207 |
| Total assets | 4,832,564 | 4,705,611 |
| Liabilities and equity | | |
| Liabilities | | |
| Current liabilities | | |
| Trade payables | 75,085 | 71,616 |
| Accrued liabilities | 323,220 | 336,270 |
| Accrued compensation | 70,039 | 53,648 |
| Deferred rent, lease incentives, and others | 11,697 | – |
| Lease liabilities | 62,312 | 42,742 |
| Total current liabilities | 542,353 | 504,276 |
| Non-current liabilities | | |
| Lease liabilities | 137,290 | 118,259 |
| Total non-current liabilities | 137,290 | 118,259 |
| Total liabilities | 679,643 | 622,535 |
| Shareholders' equity | | |
| Share capital | 1,308,902 | 1,916,642 |
| Capital surplus | 26,755,419 | 27,370,555 |
| Retained earnings (loss) | (22,164,748) | (23,845,617) |
| Other components of equity | (1,746,652) | (1,358,504) |
| Total equity attributable to owners of parent | 4,152,921 | 4,083,076 |
| Total shareholders' equity | 4,152,921 | 4,083,076 |
| Total liabilities and shareholders' equity | 4,832,564 | 4,705,611 |

(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, 2021 and 2022

| | (Thousands of yen) | |
|--|---|---|
| | Nine months ended September 30, 2021 | Nine months ended September 30, 2022 |
| Revenue | – | 2,869 |
| Business expenses | | |
| Cost of sales | – | 2,632 |
| Research and development expenses | 1,500,304 | 1,305,802 |
| Selling, general and administrative expenses | 467,916 | 421,391 |
| Total business expenses | <u>1,968,220</u> | <u>1,729,825</u> |
| Other operating income | <u>59,874</u> | <u>73,706</u> |
| Operating loss | (1,908,346) | (1,653,250) |
| Other income and expenses | | |
| Finance income | 10,086 | 10,544 |
| Finance costs | (14,455) | (9,010) |
| Other income (expenses) | <u>(17,857)</u> | <u>(29,153)</u> |
| Total other income and expenses | <u>(22,226)</u> | <u>(27,619)</u> |
| Loss before tax | <u>(1,930,572)</u> | <u>(1,680,869)</u> |
| Net loss | <u>(1,930,572)</u> | <u>(1,680,869)</u> |
| Loss attributable to Owners of parent | (1,930,572) | (1,680,869) |
| Net loss per share | | |
| Basic loss per share (Yen) | (42.50) | (35.20) |
| Diluted loss per share (Yen) | (42.50) | (35.20) |

Condensed quarterly consolidated statements of comprehensive income

Nine months ended September 30, 2021 and 2022

| | (Thousands of yen) | |
|---|---|---|
| | Nine months ended September 30, 2021 | Nine months ended September 30, 2022 |
| Net loss | (1,930,572) | (1,680,869) |
| Other comprehensive income | | |
| Items that may be reclassified to profit or loss | | |
| Exchange differences on translation of foreign operations | <u>308,469</u> | <u>388,148</u> |
| Total other comprehensive income | <u>308,469</u> | <u>388,148</u> |
| Comprehensive income | <u>(1,622,103)</u> | <u>(1,292,721)</u> |
| Comprehensive income attributable to Owners of parent | (1,622,103) | (1,292,721) |

(3) Condensed quarterly consolidated statements of changes in equity

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 |

Nine months ended September 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 | | | (1,680,869) | | (1,680,869) | (1,680,869) |
| Exchange differences on translation of foreign operations | | | | 388,148 | 388,148 | 388,148 |
| Comprehensive income | - | - | (1,680,869) | 388,148 | (1,292,721) | (1,292,721) |
| Share-based compensation expense | | 12,837 | | | 12,837 | 12,837 |
| Issuance of new shares | 607,740 | 607,740 | | | 1,215,480 | 1,215,480 |
| Issuance cost of new shares | | (5,441) | | | (5,441) | (5,441) |
| Total equity transactions with owners | 607,740 | 615,136 | - | - | 1,222,876 | 1,222,876 |
| Balance as of September 30, 2022 | 1,916,642 | 27,370,555 | (23,845,617) | (1,358,504) | 4,083,076 | 4,083,076 |

(4) Condensed quarterly consolidated statements of cash flows

| | (Thousands of yen) | |
|--|---|---|
| | Nine months ended September 30, 2021 | Nine months ended September 30, 2022 |
| Cash flows from operating activities | | |
| Net loss | (1,930,572) | (1,680,869) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation | 43,819 | 42,330 |
| Share-based compensation expense | 58,376 | 12,837 |
| Amortization of premium or discount on securities | 2,336 | (1,461) |
| Loss (gain) on sale and retirement of fixed assets | - | (2,247) |
| Finance income | (10,086) | (10,544) |
| Finance costs | 14,455 | 9,010 |
| Change in operating assets and liabilities | | |
| Trade receivables | - | (3,713) |
| Other current assets | (88,596) | 100,847 |
| Trade payables | 11,356 | (16,229) |
| Accrued liabilities | (6,162) | (89,560) |
| Accrued compensation | (17,274) | (27,154) |
| Deferred rent, lease incentives, and others | - | (11,849) |
| Other assets | 10,723 | 8,757 |
| Subtotal | (1,911,625) | (1,669,845) |
| Interest paid | (14,308) | (8,776) |
| Net cash provided by (used in) operating activities | (1,925,933) | (1,678,621) |
| Cash flows from investing activities | | |
| Interest received | 16,658 | 9,000 |
| Purchase of other financial assets | (394,378) | (581,342) |
| Proceeds from redemption upon maturity of other financial assets | 3,813,038 | 1,102,520 |
| Purchase of property, plant and equipment | (8,272) | (1,646) |
| Proceeds from collection of lease receivables | 98,718 | 24,954 |
| Proceeds from refund of leasehold and guarantee deposits | - | 12,598 |
| Net cash provided by (used in) investing activities | 3,525,764 | 566,084 |
| Cash flows from financing activities | | |
| Proceeds from issuance of ordinary shares | 319,898 | 1,212,454 |
| Proceeds from issuance of share acquisition rights | - | 3,100 |
| Payment of lease liabilities | (109,790) | (54,922) |
| Net cash provided by (used in) financing activities | 210,108 | 1,160,632 |
| Effect of exchange rate changes on cash and cash equivalents | 154,413 | 347,239 |
| Net increase in cash and cash equivalents | 1,964,352 | 395,334 |
| Cash and cash equivalents at beginning of period | 2,533,786 | 3,977,312 |
| Cash and cash equivalents at end of period | 4,498,138 | 4,372,646 |

(5) Notes to condensed quarterly consolidated financial statements

Notes on going concern assumption

Not applicable.

Significant subsequent events

Not applicable.