November 12, 2024

Summary of Financial Results for the Second Quarter of the Fiscal Year Ending March 31, 2025 (Non-consolidated) (Excerpt from Japanese version)

[Japanese GAAP]

Company name:	Kidswell Bio Corporation	Listing: Tokyo Stock Exchange
Stock code:	4584	URL: https://www.kidswellbio.com/en/
Representative:	Shinya Kurebayashi, President & CEO	
Contact:	Takahiro Kurihara, Director, Corporate Planning Dept., Corporate Strategy Div.	
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Scheduled date of filing of Annual Securities Report:	November 14, 2024
Scheduled date of payment of dividend:	-
Preparation of supplementary materials for financial results:	Yes
Holding of financial result meeting:	Yes

(All amounts are rounded down to the nearest million yen)

1. Financial Results for the Second Quarter of the Fiscal Year Ending March 31, 2025 (April 1, 2024 – September 30, 2024)

(1) Results of operations (Cumulative) (Percentages shown for net sales and incomes represent year-on-year changes)

	Net sales		Operating income		Ordinary income		Net income	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Second quarter of the fiscal year ending Mar. 31, 2025	1,749	-	-262	-	-267	-	-241	-
Second quarter of the fiscal year ending Mar. 31, 2024	-	-	-	-	-	-	-	-

	Net income per share	Diluted net income per share
	Yen	Yen
Second quarter of the fiscal year ending Mar. 31, 2025	-6.09	-
Second quarter of the fiscal year ending Mar. 31, 2024	-	-

(Note) Since we have been preparing quarterly consolidated financial statements from the first quarter of the fiscal year ending March 2025, the year-over-year change rates are not provided.

(2) Financial position

	Total assets	Net assets	Shareholders' equity ratio
	Million yen	Million yen	%
As of Sep. 30, 2024	4,645	857	16.7
As of Mar. 31, 2024	-	-	-

(Reference) Shareholders' equity

Second quarter of the fiscal year ending Mar. 31, 2025: 773 million yen Fiscal Year ended March 31, 2024: - million yen

2. Dividends

	Dividend per share				
	1Q-end	2Q-end	3Q-end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended March 31, 2024	-	0.00	-	0.00	0.00
Fiscal year ending March 31, 2025	-	0.00			
Fiscal year ending March 31, 2025 (forecasts)			-	0.00	0.00

(Note) Changes to the most recent forecasted dividend amount: None

3. Business Forecast for the Fiscal Year Ending March 31, 2025 (April 1, 2024 – March 31, 2025)

(Percentages represent year-on-year changes)

	Net sales		Operating income		Ordinary income		Net income		Net income per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
Full year	4,000	-	-1,000	-	-1.000	-	-950	-	-23.71

(Note)

Since the Company primarily manages its business on an annual basis, only the full-year forecast is presented. In addition, since we have been preparing quarterly consolidated financial statements from the first quarter of the fiscal year ending March 2025, the year-over-year change rates are not provided.

* Annotations

1. Significant changes in the scope of consolidation during this interim period: None
2. Special accounting treatments used in preparation of financial statements of the quarter: None
3. Changes in accounting policies and accounting-based estimates, and restatements
   a. Changes in accounting policies due to revisions in accounting standards, others: None
   b. Changes in accounting policies other than a) above: None
   c. Changes in accounting-based estimates: None
   d. Restatements: None

4. Number of outstanding shares (common stock)
   a. Number of shares outstanding at the end of period (including treasury shares)
      At the second quarter of the fiscal year ending March, 2025: 40,657,113 shares
      At the end of the fiscal year ended March, 2024: 38,939,913 shares
   b. Number of treasury shares at the end of period
      At the second quarter of the fiscal year ending March, 2025: 94 shares
      At the end of the fiscal year ended March, 2024: 94 shares
   c. Average number of shares outstanding during the period
      At the second quarter of the fiscal year ending March, 2025: 39,710,114 shares
      At the third quarter of the fiscal year ended March, 2024: 32,378,635 shares

*This summary report is not subject to audit procedures.

*Cautionary statement with respect to forward-looking statements, and other special items

(Notes to information regarding future)

Forecasts regarding future performance in these materials are based on assumptions judged to be valid and the information available to the Company at the time these materials were made. These materials on future performances are not promises by the Company. Actual performance may differ significantly from these forecasts for several reasons.

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I. Financial Results for the current fiscal quarter

Since the Group has been preparing consolidated financial statements since the current fiscal year, no comparative analysis with the previous fiscal year has been made. As for this quarterly cumulative period from April 1, 2024 to September 30, 2024 consolidated financial results, the sales was 1,749,911 thousand yen, R&D expenses was 340,907 thousand yen, operating loss was 262,520 thousand yen, ordinary loss was 267,993 thousand yen, and net loss attributable to owners of the parent of the Company was 241,794 thousand yen.

(1) Business updates

a) Biosimilars business

In our biosimilars business, we are committed to commercializing biosimilars that offer the same quality, safety, and efficacy as their reference biologics. This approach supports patients in continuing their treatments by reducing their financial burden and contributes to the sustainability of health insurance systems through healthcare cost reduction.

Looking forward, a wide range of biologics developed by major domestic and international pharmaceutical companies will continue to enter the market and eventually reach the end of their patent and re-examination periods, providing ample business opportunities in the biosimilars market. Additionally, in Japan, recent initiatives such as setting biosimilar penetration targets and introducing reimbursement incentives by the Ministry of Health, Labour, and Welfare are expected to drive a steady increase in demand and expand the market size. However, few companies in Japan possess the expertise, track record, and talent required for biosimilar development. Leveraging our accumulated experience, know-how, and insights, we aim to contribute to the commercialization of numerous biosimilars while achieving growth that surpasses the pace of market expansion.

To date, we have been involved in the development of four of the 18 biosimilar products currently approved in Japan, all of which were launched as first-to-market products. Consequently, the revenue from these launched products has grown to exceed our fixed costs, excluding R&D expenses. We anticipate that this business will continue to generate stable, recurring revenue in the long term. Therefore, we position it as a key business for maximizing corporate value under our unique 'balance of stability and growth' strategy as a biotech venture.

In pursuit of further growth through the creation of new revenue streams in the biosimilars business, we entered into a business alliance agreement in June 2024 with Chiome Bioscience Inc. (hereinafter “Chiome”), a company with strong capabilities in the development of antibody therapeutics. Based on this agreement, the two companies will jointly develop selected new biosimilar candidates by pooling their bioscience talent, expertise, and experience in biopharmaceutical development. Development costs will be shared, and efforts will primarily focus on co-developing cell lines and manufacturing processes. Revenue from any cell lines or manufacturing processes developed through this collaboration, whether through licensing or transfer to pharmaceutical companies, along with revenue from providing development support to these companies, will be profit-shared between the two parties. This partnership aims to establish an effective, synergy-driven collaboration model.

Alongside the formalization of development plans for our fifth biosimilar product and beyond under this alliance, we are actively engaged in discussions under confidentiality agreements with several domestic and international pharmaceutical companies. We aim to conclude joint commercialization agreements promptly, with an eye toward expansion into overseas markets.

Regarding efforts to optimize capital efficiency and profit margins during this interim consolidated cumulative period, we have been in ongoing discussions with our pharmaceutical partners to adjust payment terms to accommodate increased working capital needs driven by strong demand growth for GBS-007 and GBS-010. Additionally, we are negotiating adjustments in supply prices to reflect the rising manufacturing costs caused by inflation overseas and the yen’s depreciation.

To ensure stable supply and reduce manufacturing costs, we have also focused on technology transfer and process development for a new contract manufacturer for some biosimilar APIs. While we have mostly completed the development process for Pharmaceuticals and Medical Devices Agency (PMDA) approval as planned, unforeseen additional requirements have led to a delay in the approval timeline by approximately six months. Consequently, our anticipated cost reductions and improved profitability are expected to be realized from FY2026.

b) Cell therapy business (regenerative medicine)

As a growth business supporting our significant value enhancement, our cell therapy business (regenerative medicine) is focused on developing innovative regenerative medicine products based on stem cells from human exfoliated deciduous teeth (SHED) derived from healthy donors’ baby teeth, utilizing technology acquired through the 2019 acquisition of Cell Technology, Inc. Cell therapy, or regenerative medicine, has the potential to treat difficult diseases and rare conditions that previously lacked effective treatments. The discovery of iPS cells, a foundational technology in this field, led to Professor Shinya Yamanaka of Kyoto University receiving the Nobel Prize in Physiology or Medicine in 2012, spurring accelerated research and commercialization efforts worldwide.

SHED, derived from pediatric tissue, is younger and has higher proliferative potential compared to mesenchymal stem cells

(MSCs) derived from bone marrow or adipose tissue. This allows for the mass production of regenerative medicine products from a single baby tooth. Additionally, unlike products sourced from overseas donors, SHED offers the advantage of being readily available in Japan, ensuring stable and sustainable domestic production.

Since 2019, we have pursued SHED science through collaboration and joint research with our partners and academia, focusing on developing manufacturing methods for regenerative medicine products based on SHED. In March 2020, the Ministry of Economy, Trade, and Industry published guidance on legal, ethical, and social issues related to human (allogeneic) cell sourcing, further strengthening the regulatory environment. In August 2022, we completed the construction of a clinical-grade SHED Master Cell Bank (MCB) for Japan, and in March 2024, we achieved compliance with FDA standards, laying the groundwork for clinical development domestically and internationally. Additionally, we have established 'S-Quatre®,' a system encompassing donor recruitment, extraction by affiliated medical institutions, and MCB production in GMP-compliant facilities. This platform supports not only our pipeline but also serves other companies developing regenerative medicine products and cell-related pharmaceuticals, such as exosomes, by providing MCBs.

Our proprietary manufacturing process produces SQ-SHED (previously KWB-SHED, renamed following the establishment of S-Quatre Corp.), which differs in gene expression profiles from MSCs derived from other tissues and even from SHED produced by conventional methods. It exhibits higher gene expression linked to neurogenesis, angiogenesis, and cell migration, as well as increased production of related protein growth factors. These enhanced biological activities have been validated through cell function assays and animal model testing, leading to a patent application in October 2022.

Leveraging these distinctive features of SQ-SHED, we have focused on cerebral palsy (chronic phase) and bone diseases as potential therapeutic targets. Last fiscal year, clinical research on autologous (patient-derived) SHED for chronic-phase cerebral palsy began under the leadership of Nagoya University. Since enrolling the first patient in October 2023, all patients have been registered, with SHED administration and follow-up underway. For our clinical trial on allogeneic (donor-derived) SHED targeting cerebral palsy, using an MCB already established in Japan, we are currently preparing trial materials and consulting with the PMDA. This trial is expected to be led by a development partner, with plans to finalize an agreement within the current fiscal year (ending March 2025) and submit a clinical trial notification in FY2025. We are also working on the development framework for clinical studies overseas, including site selection, in collaboration with global CROs.

For bone disease, in September 2024, we entered a joint research agreement with Dokkyo Medical University and HOYA Technosurgical Corporation to develop a novel therapy for ischemic bone disease.

In parallel to ongoing clinical development of our first-generation SHED, we are advancing basic research and process development for a second generation of enhanced SQ-SHED, aiming to meet higher therapeutic goals and expand applications to new disease areas through genetic modifications and optimized culturing techniques. We will continue to accelerate efforts to transition this enhanced generation to clinical stages.

c) Other initiatives to enhance business value

Under the new management structure established last fiscal year, we have been working toward maximizing corporate value and achieving early recovery and growth in our stock price. This involves the efficient use of management resources, optimizing financing methods, and enhancing the visibility of business value.

To improve the efficiency of resource allocation, we have strategically decided to concentrate our resources on the biosimilars and cell therapy (regenerative medicine) businesses, as noted above. Through structural reforms and strengthening inter-business collaboration, we are leveraging our accumulated R&D knowledge and expertise in each business area to enhance and streamline research and development activities. Additionally, we are prioritizing our various R&D pipelines based on factors such as progress and business potential, with a focus on continuous growth and the rationalization of R&D investments.

In optimizing financing, the establishment of S-Quatre Corp. allows us to dedicate resources solely to the biosimilars business, while S-Quatre focuses on the cell therapy business. This structure enables us to pursue financing strategies tailored to each business's unique characteristics and stage. We have already engaged in discussions under confidentiality agreements with multiple potential business partners, not only with financial institutions like banks and investment funds but also considering capital partnerships with business candidates in each field. To improve capital efficiency, particularly in the biosimilars business, we have initiated adjustments in payment terms with partner pharmaceutical companies. These efforts are already yielding improvements in accounts receivable turnover, thereby compressing the working capital that had increased significantly due to rising demand for biosimilars. We will continue to optimize R&D investments and working capital, manage our capital needs, expand the use of indirect financing, and seek funding from business partners to reduce our dependency on the equity market.

For enhancing business value visibility, the creation of S-Quatre Corp. enables us to clearly report profitability in the biosimilars business as a standalone entity, improving the quality of our communications with the stock market. Leveraging the disclosure system for international institutional investors established last year, we actively participate in partnering events, such as the BIO International Convention, to strengthen dialogue with foreign institutional investors. Additionally, we are fostering active

communication with analysts and media to deepen understanding of our strengths, broaden our outreach through reports and articles, and plan investor presentations for individual investors across wider regions and demographics. Through these efforts, we are enhancing our IR and PR activities.

(2) Outlook

Our biosimilars business, which provides a stable revenue foundation, has seen replacement rates for GBS-001 and GBS-011 exceed 80% from the reference biologics, with our partners' market share remaining steady. For GBS-007, launched in December 2021, no competing biosimilars have entered the market, and with the additional indication approval in September 2023, replacement rates from the reference biologic and our partner's market share have further expanded. Similarly, GBS-010, our fourth product approved in September 2023, continues to benefit from high market demand in the absence of other biosimilar competition.

Given these favorable market conditions and the Japanese Ministry of Health, Labour, and Welfare's measures to promote biosimilar adoption, we anticipate strong mid-term revenue growth in this segment, primarily driven by GBS-007 and GBS-010. In response to anticipated demand growth from our partner pharmaceutical companies, we are enhancing our stable supply framework, adjusting manufacturing plans, and negotiating adjustments to payment terms to address the increased working capital needs. Supply volume for the current fiscal year has already been finalized in coordination with our partners and contract manufacturers, with these impacts reflected in our latest consolidated earnings forecast disclosed today. Additionally, we are negotiating with partners to adjust supply prices in response to rising manufacturing costs influenced by overseas inflation and yen depreciation. We remain committed to analyzing external factors and optimizing both capital efficiency and profitability.

To strengthen our stable supply system and reduce manufacturing costs, we have continued to transfer technology and develop manufacturing methods for a new contract manufacturer for certain biosimilar APIs. Development for PMDA approval has mostly proceeded as planned, though additional requirements have led to an anticipated six-month delay in approval timing. Consequently, the cost-saving effects of these initiatives are expected to contribute to profitability starting in FY2026.

Our cell therapy business, positioned as a future growth driver, continues to advance clinical development for chronic-phase cerebral palsy. For the Nagoya University-led clinical research on autologous SHED that began last fiscal year, we are providing ongoing support, including observation of patients who have already received SHED treatment and production of SHED for upcoming patients. Concurrently, we are preparing clinical trial materials and advancing discussions with our development partner for allogeneic SHED in Japan, with a target to submit a clinical trial application by FY2025. For the overseas market, we are progressing on clinical development for chronic-phase cerebral palsy with allogeneic SHED, including establishing a development framework with overseas CROs. Additionally, as mentioned, research on first-generation SHED for bone diseases is making progress.

To achieve higher therapeutic goals and expand into new disease areas, we are enhancing the functionality of SQ-SHED through genetic modifications and optimized culturing techniques, aiming to accelerate the clinical development of this second-generation SHED. We are also exchanging information and conducting discussions with potential development partners to drive this initiative forward.

(3) Earnings forecast

As mentioned above, in the biosimilars business, discussions and adjustments with partner pharmaceutical companies and contract manufacturing organizations (CMO) have been finalized, solidifying the production and delivery plans for this fiscal year. Accordingly, the earnings forecast for the current fiscal year is detailed in today's notice, "Consolidated Earnings Forecast," as well as on page 1 of the second-quarter financial report, section "3. Consolidated Earnings Forecast for the Fiscal Year Ending March 2025 (April 1, 2024 – March 31, 2025)."

During this interim consolidated accounting period, concerns have arisen over uncertainties surrounding corporate performance and economic outlook due to rapid foreign exchange fluctuations and domestic and international political developments. However, the demand for pharmaceuticals, including biosimilars, is relatively unaffected by economic trends. Therefore, sales in the biosimilars business are expected to grow. Additionally, since our group manufactures all biosimilar active pharmaceutical ingredients (APIs) through overseas CMOs and outsources a portion of research and development activities for both the biosimilars and cell therapy businesses to foreign companies, further yen appreciation in the foreign exchange market could lower the cost of goods sold and R&D expenses in the latter half of this fiscal year, potentially boosting profits. On the other hand, significant inflation or a steep depreciation of the yen could negatively impact this fiscal year's earnings and those of subsequent years. Should such circumstances arise, we will carefully examine the situation and disclose relevant information promptly.

(4) Mid-term management plan

Our group announced the mid-term management plan, KWB2.0, on May 12, 2022, aiming to achieve sales of 3 billion yen and operating profit of 1 billion yen in FY2025. Since then, we have been steadily pursuing business activities to achieve these goals. In the biosimilars business, we successfully launched our fourth product as planned, and in the cell therapy business, we entered the

clinical development stage within FY2022, also according to the plan. Meanwhile, we have actively adapted to changing external conditions by undertaking unplanned transformations, such as initiating new biosimilar development and transforming our business model to ensure sustainable growth in the biosimilars business, establishing the Tokyo Lab to accelerate research and development of second-generation SHED, incorporating spin-offs for appropriate fundraising, and suspending research activities in the biopharmaceutical business.

In the biosimilars business, competition anticipated at the time of planning did not materialize, and the social significance of biosimilars, which contribute to reducing healthcare costs, has increased. Consequently, the business has grown steadily, with sales for this fiscal year expected to reach 4 billion yen. Moreover, supported by improving market conditions and promotion of biosimilars by the Ministry of Health, Labour and Welfare, we have begun initiatives for new biosimilars in collaboration with Chiome Bioscience to ensure sustainable growth in the biosimilars business. However, external factors such as inflation and yen depreciation, exceeding 160 JPY/USD at one point, despite the plan assuming 120 JPY/USD, have significantly impacted profit margins.

To ensure the stable supply and cost reduction of certain biosimilar APIs, we have been developing manufacturing processes and transferring technology to new CMOs. While development toward PMDA approval has progressed mostly on schedule, additional tasks have delayed approval by approximately six months. To address this delay, after thorough discussions with partner companies, we decided to place additional orders with existing CMOs to maintain a stable supply of the biosimilar. Once these additional APIs are utilized, we plan to transition to lower-cost APIs produced by the new CMOs, with the switch expected to occur in the FY2026.

In the cell therapy business, first-generation SHED has entered clinical development domestically, and preparations for clinical development overseas are progressing in collaboration with external organizations. Additionally, multiple second-generation SHED projects are advancing toward early clinical development. As a result, research and development activities have progressed beyond initial expectations, leading to an anticipated increase in R&D investments compared to those planned during the original strategy formulation.

The foundation for achieving operating profitability in FY2025, namely cost reduction strategies in the biosimilars business through a new manufacturing framework, has come into clearer view with progress toward PMDA approval. Despite a six-month delay in obtaining approval, we expect to see cost reduction benefits in FY2026, paving the way for operating profitability. As for the FY2026 outlook, we will finalize manufacturing plans to meet growing demand for biosimilars, negotiate supply prices with partner pharmaceutical companies based on future exchange rate trends, and explore measures to improve the efficiency of R&D expenditures through partnership activities. Once details have been thoroughly examined, we will disclose them promptly.

II. Financial statements and notes to financial statements

(A) Balance sheet

	(in thousand yen)
	As of the end of the current fiscal quarter (September 30, 2024)
Assets	
Current assets	
Cash and cash equivalents	1,695,373
Accounts receivable	507,843
In-process inventory	752,698
Advance payments	1,294,971
Other current assets	101,886
Total current assets	4,352,772
Non-current assets	
Tangible fixed assets	1,254
Intangible fixed assets	1,147
Investments and other assets	
Investment securities	267,593
Other investments and assets	23,025
Total Investments and other assets	290,618
Total non-current assets	293,019
Total assets	4,645,792
Liabilities	
Current liabilities	
Trade payables	57,244
Long-term debts to be repaid within one year	622,040
Account payable	209,511
Income taxes payable	36,690
Contract liabilities	1,257,283
Others	10,430
Total current liabilities	2,193,200
Non-current liabilities	
Corporate bonds	500,000
Long-term debts	1,009,440
Reserve for retirement allowance	41,778
Deferred tax liabilities	44,178
Total non-current liabilities	1,595,396
Total liabilities	3,788,597
Shareholders' equity	
Shareholders capital	
Common stock	2,159,537
Capital Surplus	11,465,138
Retained Earnings	−12,950,877
Treasury stock	−73
Total shareholders capital	673,725
Valuation difference on securities	100,196
Equity warrants	83,274
Total shareholders' equity	857,195
Total liabilities and shareholders' equity	4,645,792

(B) Income statement

	(in thousand yen)
	This quarterly cumulative period (April 1, 2024 to September 30, 2024)
Gross sales	1,749,911
Cost of goods sold	1,257,582
Gross profit	492,329
Selling, general and administrative expenses	
R&D expenses	340,907
Other expenses	413,942
Total selling, general and administrative expenses	754,850
Operating loss (-)	-262,520
Non-operating income	
Interest income	122
Material Sale income	1,080
Compensation received	21,816
Miscellaneous income	328
Total non-operating income	23,224
Non-operating expenses	
Interest expense	21,141
Interest on corporate bonds	1,571
Foreign exchange loss	5,630
Miscellaneous loss	354
Total non-operating expenses	28,697
Ordinary loss (-)	-267,993
Extraordinary gain	
Reversal of equity warrant	42,099
Total extraordinary gain	42,099
Extraordinary loss	
Loss on valuation of investment securities	14,999
Total extraordinary loss	14,999
Net loss for the year before tax adjustment (-)	-240,894
Corporate, residential and enterprise taxes	900
Total corporate and other taxes	900
Net loss for the period (-)	-241,794
(breakdown)	
Net loss for the period attributable to parent company shareholders	-241,794
Comprehensive income for the period	-241,794
(breakdown)	
Comprehensive income for the period attributable to parent company shareholders	-241,794

(C) Statement of cash flows

	(in thousand yen)
	This quarterly cumulative period (April 1, 2024 to September 30, 2024)
Cash flows from operating activities	
Net loss for the year before taxes adjustments (-)	−240,894
Depreciation expenses	450
Loss on valuation of investment securities (- means increase)	14,999
Interest or dividends received	−122
Interest expense	21,141
Interest on corporate bonds	1,571
Changes in trade receivables (- means increase)	373,563
Changes in inventory (- means increase)	122,955
Changes in advance payments (- means increase)	−555,403
Changes in trade payables (- means decrease)	−27,896
Changes in accrued expenses (- means decrease)	−171,074
Changes in contract liability (- means decrease)	139,509
Other changes	63,110
Sub-total	−258,089
Interest and dividends received	122
Interest payment	−28,934
Payment of corporate and other taxes	−1,525
Cash flows from operating activities	−288,426
Cash flows from investing activities	
Proceeds from the collection of loans from affiliates	−2,954
Cash flows from investing activities	−2,954
Cash flows from financing activities	
Repayment of long-term debt	−443,520
Proceeds from issuance of equity warrants	198,862
Cash flows from financing activities	−244,657
Increase/decrease in cash and cash equivalents (- means decrease)	−536,038
Cash and cash equivalents at the beginning of the year	2,231,411
Cash and cash equivalents at the end of the period	1,695,373

(D) Notes to financial statements

(Notes on material changes of shareholders' equity)

During the cumulative period of the second quarter, the 8th, 12th, 14th and 18th series of stock acquisition rights were exercised. As a result, capital and capital reserve increased by 122,813 thousand yen respectively, and as of the end of the second quarter of the fiscal year, capital was 2,159,537 thousand yen and capital reserve was 11,465,138 thousand yen.

(Notes on going concern assumption)

There is no reporting item applicable to this matter.