

# **Financial Results for 3Q FY 2022**

## **(Fiscal Year Ending March 31, 2023)**

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**February 7, 2023**

**Kidswell Bio Corporation**



# **Business and Financial Highlights in 3Q FY 2022**

## Financial Highlights in 3Q FY 2022

- ✓ Expanding to the biosimilar sales contributed by sales and profit growth of GBS-007.
- ✓ Expecting to record most of R&D expenses for GBS-007 manufacturing cost reduction and cell therapy business, etc. in 4Q FY 2022.
- ✓ Improving operating income from the previous year due to prioritizing investments and continuous cost reduction.

## Business Highlights in 3Q FY 2022

### Cell Therapy (Regenerative Medicine)

- Transferred all shares of JRM (Japan Regenerative Medicine Co., Ltd.) to Metcela Inc. (Development of JRM-001 is led by Metcela, Inc.).
- Completion of GMP-compliant SHED MCB manufacturing and supply system.
- Executed a master service agreement with Showa Denko Materials Co., Ltd. for the development of manufacturing process for the regenerative medicine products utilizing SHED and manufacturing investigational new drugs.
- Patent application on cell therapy for cerebral palsy utilizing SHED with Tokai National Higher Education and Research System (Nagoya University).
- Publication of the research articles in collaboration with Hamamatsu University School of Medicine (Proof of concept of the potential therapeutic application of next generation SHED for brain cancer).
- **Proceeding with the preparation for clinical research of SHED with Nagoya University.**

### New Biologics

- Executed a research collaboration agreement with Chiome Bioscience Inc. (Chiome) on the development of antibody drugs.
- **A patent grant for anti-RAMP2 antibodies which inhibit the formation of new blood vessels with a new mechanism.**

### Biosimilars

- Strong sales due to more orders of GBS-007 than expected.
- **Approval of additional indication of GBS-007.**

### Others

- Sifted to non-consolidated financial result from 1Q FY 2022 due to transfer of the subsidiary
- Financing for working capital and facility reinforcement due to increased order of GBS-007

# Financial Results in 3Q FY 2022 (PL): Income Statement



Unit : thousands yen

| Subject                                      | Results for 3Q FY2021<br>(Consolidated) | FY 2022 ending March 31, 2023<br>(Non-consolidated) |                    | Highlights   |                   |               |
|--|---|---|--------------------|--|-------------------|---------------|
|  |   | Result for 3Q                                       | Year-on-year ratio |  | Forecast          | Progress rate |
| <b>Gross sales</b>                           | <b>1,383,239</b>                        | <b>1,726,862</b>                                    | <b>125%</b>        | <ul style="list-style-type: none"> <li>Expanding the biosimilar sales led by sales growth of GBS-007.</li> <li>Recorded the sales related to completion of GMP-compliant SHED MCB.</li> <li>Although there is a delay of shipment of some products, the sales are generally in line with the original plan.</li> </ul>   | <b>2,900,000</b>  | <b>60%</b>    |
| Cost of goods sold                           | 458,501                                 | <b>654,042</b>                                      | 143%               |  | 1,700,000         | 38%           |
| (Cost of sales ratio)                        | 33%                                     | 38%   |                    |  | 59%               |               |
| Gross profit                                 | <b>924,737</b>                          | <b>1,072,819</b>                                    | <b>116%</b>        | <ul style="list-style-type: none"> <li>Gross profit expansion due to strong sales in biosimilar business.</li> </ul>   | <b>1,200,000</b>  | <b>89%</b>    |
| Selling, general and administrative expenses | 1,357,696                               | <b>1,208,342</b>                                    | 89%                | <p>R&amp;D is generally progressing, and most of development expenses are expected to be recorded in the 4Q FY 2022.</p> <ul style="list-style-type: none"> <li>Continuously reducing the manufacturing cost of GBS-007.</li> <li>More investment in cell therapy business for development of SHED products for clinical use.</li> </ul> <p>Other selling, general and administrative expenses</p> <ul style="list-style-type: none"> <li>Increased payment of royalty due to strong sales in biosimilar business.</li> <li>Continuously streamlining expenses.</li> </ul> | 2,180,000         | 55%           |
| (Cost of sales ratio)                        | 98%                                     | 70%   |                    |  | 75%               |               |
| R&D expenses                                 | 770,421                                 | <b>579,055</b>                                      | 75%                |  | 1,400,000         | 41%           |
| (Cost of sales ratio)                        | 56%                                     | 34%   |                    |  | 48%               |               |
| Other expenses                               | 587,275                                 | <b>629,287</b>                                      | 107%               |  | 780,000           | 81%           |
| Operating loss                               | <b>-432,958</b>                         | <b>-135,523</b>                                     | --                 | <ul style="list-style-type: none"> <li>Good performance of biosimilar business such as strong sales of GBS-007</li> <li>Operating income improved due to prioritizing investments and continuous cost reduction.</li> </ul>  | <b>-980,000</b>   | --            |
| Net loss                                     | -460,046                                | -194,023  | --                 |  | -999,000          | --            |
| Net loss for the quarter                     | <b>-94,401</b>                          | <b>-194,930</b>                                     | --                 | <ul style="list-style-type: none"> <li>This quarterly net income decreased due to recording the income from sale of investment securities as extraordinary income in the FY 2021 but is expected to improve significantly compared with the full-year forecast.</li> </ul>   | <b>-1,000,000</b> | --            |

- The biosimilar business keeps well. The cell therapy business also progresses steadily including the manufacturing process development of SHED for clinical development.
- Net sales increased. Profit increased at each profit stage, except for quarterly net income, which was due to special factors in the previous fiscal year.
- Large-scale R&D investment in GBS-007 manufacturing and development of SHED manufacturing process development for clinical development in 4Q FY 2022.

# Financial Results in 3Q FY 2022: Balance Sheet

Unit : thousands yen

| Subject  | 4Q FY2021<br>Consolidated | 2Q FY 2022<br>Non-Consolidated | Highlights   |
|--|---------------------------|--------------------------------|--|
| Current assets   | 3,294,940                 | 3,948,993                      |  |
| (Cash and cash equivalents)                                      | 1,160,934                 | 1,499,615                      | ✓ Cash increased due to long-term loan from Mizuho Bank and the issuance of convertible bonds (CBs). |
| (Trade receivables)  | 461,854                   | 826,845                        | ✓ Due to strong sales growth of GBS-007  |
| (Products)   | 200,118                   | 312,683                        |  |
| (In-process inventory)   | 788,696                   | 408,427                        |  |
| (Advance payments)   | 495,544                   | 850,399                        |  |
| (Long-term debts to be repaid within one year from a subsidiary) | 600,000                   | —                              |  |
| (Other current assets)   | 161,537                   | 51,022                         |  |
| (Allowance for doubtful accounts)                                | -573,745                  | —                              |  |
| Non-current assets   | 175,396                   | 224,380                        |  |
| <b>Total assets</b>  | <b>3,470,336</b>          | <b>4,173,374</b>               |  |
| Current liabilities  | 1,111,168                 | 780,463                        | ✓ Reversal of provision for loss of orders   |
| Non-current liabilities  | 656,260                   | 1,704,655                      | ✓ Due to long-term loan from Mizuho Bank and the issuance of the 4 <sup>th</sup> series of CBs, etc. |
| Total liabilities  | 1,767,428                 | 2,485,118                      |  |
| Total shareholders' equity                                       | 1,702,908                 | 1,688,256                      |  |
| <b>Total liabilities and shareholders' equity</b>                | <b>3,470,336</b>          | <b>4,173,374</b>               |  |

- The net asset ratio has been reduced due to long term loan and issuance of CBs, but the level of liquidity has been improved.
- Accelerating investment in cell therapy business with increased liquidity and operating cash flow from biosimilars.

# Key Updates in Mid-Term Strategic Plan

 **Progressing as scheduled**

**Licensing-out**    **SHED**    CSC JRM-001

**R&D**    **Cell Therapy SHED CSC**    **New Biologics**    **Biosimilar 4<sup>th</sup> Product**

**Technology Development**    **SHED Supply System Completion of MCB Completed**    **Designer Cell**    **High-Yield Protein Producing Cell Lines**

**Profit Expansion**    **GBS-001 Cost Reduction Completed**    **GBS-007 Cost Reduction**

**Stable Profit**    **GBS-001 Sales**    **GBS-011 Royalties**    **GBS-007 Sales**

**UPDATE !**  
**A patent grant for anti-RAMP2 antibodies**

**UPDATE !**  
**Approval of additional indication of GBS-007**  
More treatment options for patients

**Strengthen profit structure led by GBS-007**

# **Key updates in cell therapy (SHED) business**

- Established SHED products platform based on S-Quatre® with the completion of GMP-compliant SHED MCB.
- Improving SHED business value due to starting preparation for clinical research of the 1<sup>st</sup> generation SHED.
- Accelerating R&D activities of the 2<sup>nd</sup> generation SHED to maximize the value of SHED platforms, pursue synergies between SHED and other modalities and global expansion.



\* Master Cell Bank

## 1<sup>st</sup> Generation SHED

Starting the preparation for initiating clinical research/ clinical trial

- Clinical research on cerebral palsy, one of the target diseases of 1<sup>st</sup> generation SHED
- Clinical research/ clinical trials for other disease

## 2<sup>nd</sup> Generation SHED

Identifying target diseases based on the results from collaborative research with academia, etc., and proceeding the preparation for starting clinical trials globally as well as domestically.

## Other Modalities

Identifying partners and supporting R&D to create new seeds utilizing SHED as a raw material.



## Various SHED research data through collaborative researches with academies

| Development Product | Target disease   | Symptom                              | Existing Treatment                       | Development stage               | Number of patients (Domestic) ※2                   | Number of patients (Global) ※2                            | Partners   |
|---------------------|--|--------------------------------------|--|---------------------------------|--|---|--|
| 1st Generation SHED | <b>Pediatric disease</b><br>Cerebral palsy                       | Quadriplegia and Posture disorder    | None                                     | Preparing for clinical research | 2,000 patients per year, 30,000 patients in total  | 100,000 patients per year, 1.7 millions patients in total | Nagoya University, Tokyo Medical and Dental University |
|                     | <b>Pediatric disease</b><br>Congenital Isolated Hypoganglionosis | Intestinal obstruction               | Enterectomy, colostomy                   | Preclinical                     | 100 patients                                       | —   | Mochida Pharmaceutical                                 |
|                     | <b>Incl. pediatric disease</b><br>Spinal cord injury             | Loss of motor function and sensation | None                                     | Preclinical                     | 5,000 patients per year, 100,000 patients in total | 25,000 patients per year, 500,000 patients in total       | Nagoya University                                      |
|                     | Ophthalmologic disease, etc.                                     | ※1                                   | ※1                                       | Preclinical                     | ※1   | ※1  | Gifu Pharmaceutical University                         |
|                     | Non-union fractures  | Chronic pain, gait disturbance       | None                                     | Research                        | 100,000 patients per year                          | —   | Hokkaido University                                    |
|                     | <b>Pediatric disease</b><br>Cleft lip and palate                 | Eating and speech disorder           | Lip arthroplasty + iliac bone graft      | Research                        | 2,000 patients per year                            | 15 out of 10,000 newborns                                 | ORTHOREBIRTH   |
| 2nd Generation SHED | Brain cancer   | Poor life prognosis                  | Surgery, radiation therapy, chemotherapy | Research                        | 20,000 patients per year                           | 830,000 patients in total                                 | Hamamatsu University School of Medicine                |
|                     | <b>Incl. pediatric disease</b><br>Spinal cord injury             | Loss of motor function and sensation | None                                     | Research                        | 5,000 patients per year, 100,000 patients in total | 25,000 patients per year, 500,000 patients in total       | Nagoya University                                      |
|                     | Neurodegenerative disease, etc.                                  |                                      |  | Research target                 |  |   |  |
| Other Modalities    | Autoallergic disease, etc.                                       |                                      |  | Research target                 |  |   |  |
|                     | Exosomes and mitochondria, etc.                                  |                                      |  | Research target                 |  |   |  |

## Identifying target diseases based on preclinical data through in-house and collaborative research with academias and accelerating a preparation for clinical research



January 22, 2020  
Gene Techno Science Co., Ltd.  
Code: 4584 (TSE Mothers)  
Masaharu Tani, President & CEO

### Announcement of Joint Research Agreement for Cerebral Palsy with 3 Institutes

Tokyo, January 22, 2020 – Gene Techno Science Co., Ltd. (“GTS”) executed a joint research agreement with Tokyo Metropolitan Institute of Medical Science, Nagoya University Hospital, and Tokyo Medical and Dental University for research and development of new therapeutic treatments for cerebral palsy.



October 24, 2022  
Kidswell Bio Corporation  
Code: 4584 (TSE Mothers)  
Masaharu Tani, President & CEO

Announcement of a patent application on cell therapy for cerebral palsy utilizing SHED with Tokai National Higher Education and Research System  
(Extracted from Japanese version)

Tokyo, October 24, 2022 – Kidswell Bio Corporation (KWB) is delighted to announce that the joint patent application agreement was executed with Nagoya University (Tokai National Higher Education and Research System is established in April 2020 including Nagoya University and Gifu University) and the patent on the cell therapy for cerebral palsy utilizing SHED (stem cells from human exfoliated deciduous teeth) was applied through the collaborative research with KWB and

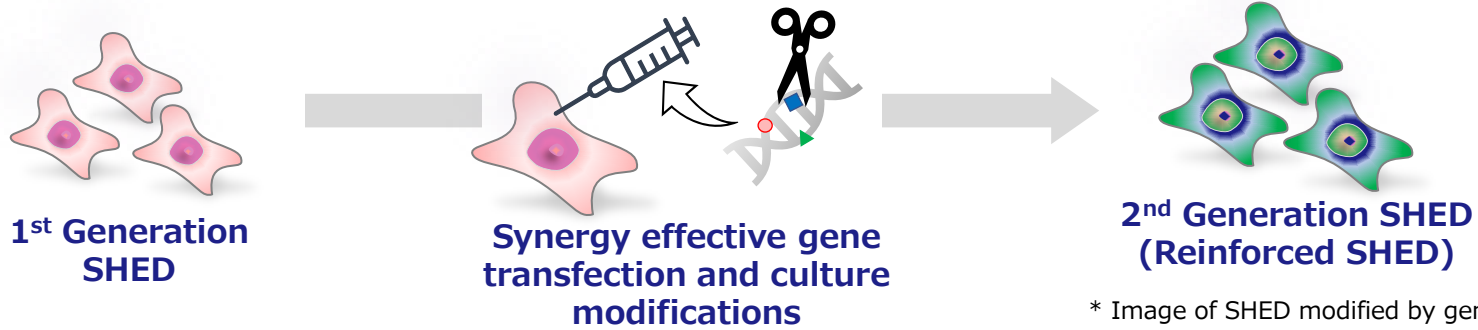


December 7, 2022  
Kidswell Bio Corporation  
Code: 4584 (TSE Mothers)  
Masaharu Tani, President & CEO

Announcement of research results at the annual meeting of 66<sup>th</sup> Japan Society for Neonatal Health and Development  
-Therapeutic effects of SHED on chronic cerebral palsy model-

Tokyo, December 7, 2022 – Kidswell Bio Corporation (KWB) is delighted to announce that the research results for chronic cerebral palsy model was announced by Neonatal division, Center for Maternal-Neonatal Care, of Nagoya University Hospital (hereafter Nagoya University) at the annual meeting of 66<sup>th</sup> Japan Society for Neonatal Health and Development held from Nov. 24 to 26, 2022. KWB has been conducting R&D activities for the launch of new treatment methods for cerebral palsy with Nagoya University utilizing stem cells from human exfoliated deciduous teeth (SHED) and SHED showed improvement effects for neurological symptoms in the chronic phase, which has been challenging in cerebral palsy treatment.

## Accelerating SHED modified by gene transfection and culture methods to enhance therapeutic efficacy



\* Image of SHED modified by gene transfection

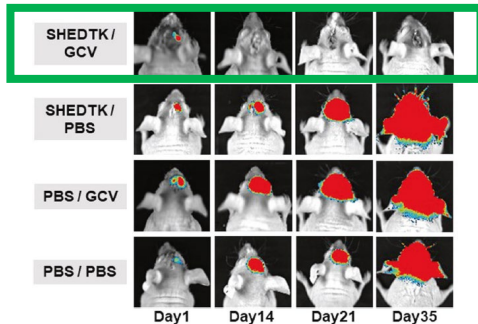
### Target Diseases of the 2<sup>nd</sup> Generation SHED

#### 1. Brain cancer

Creating epoch-making antitumor drug to with combined administration of the SHED engineered to express thymidine kinase (TK), and ganciclovir.

(Research articles in collaboration with Hamamatsu Univ. School of Medicine)

*Cancer Gene Ther.* 2022

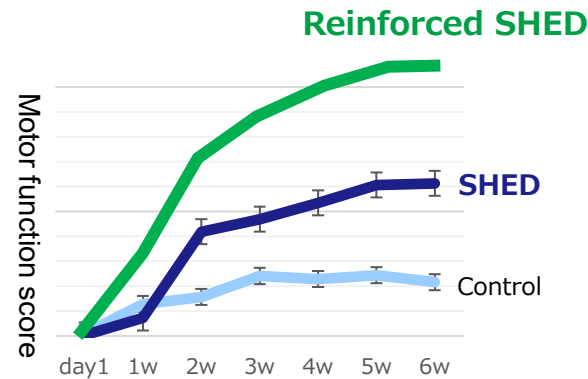


**Disappeared brain tumor by administration of SHED TK**

#### 2. Spinal cord injury

Creating “reinforced SHED” by new gene transfection

(Collaborative research with Nagoya Univ.)

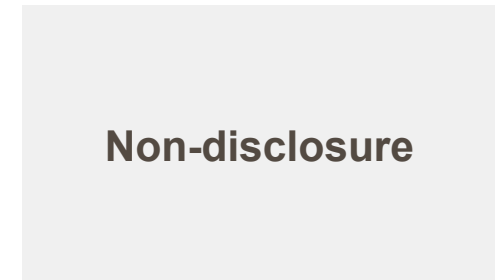


#### 3. Other target disease

(Alzheimer disease, ALS, muscular dystrophy, etc.)

Creating SHED with cell directionality for disease sites by new gene transfection and culture method modification.

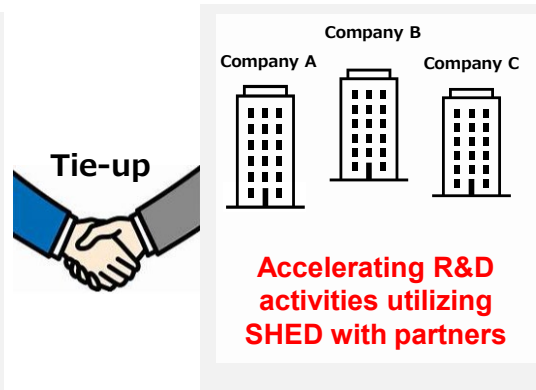
(In-house research or collaborative research with BioMimetics Sympathies)



## Creating other modalities using SHED as a raw material with partners



\* Master Cell Bank



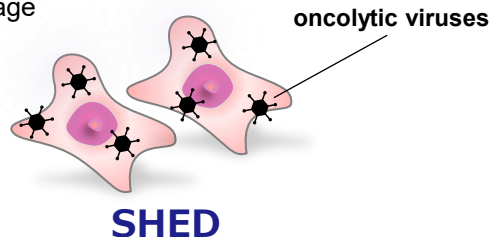
\* Image from partner companies' R&D activities to launching

## Synergies with other modalities utilizing SHED

### 1. Oncology

Utilizing SHED as a delivery system for oncolytic viruses

\*Image

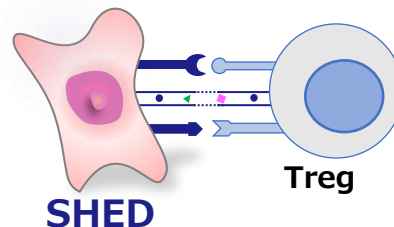


### 2. Autoallergic disease

(Type 1 diabetes, rheumatism, multiple sclerosis)

Utilizing SHED as a manufacturing tool for Treg cell medicine

\*Image



### 3. Other target diseases

(Heart failure, respiratory failure, mitochondrial disease)

Utilizing SHED as a raw material for new drug candidates, such as exosomes and mitochondria

\*Image



Active discussions are ongoing with several potential partners.

# Accelerating our R&D activities to realize our vision for patients who are waiting for new medical treatments

- Proceeding with the preparation for clinical research/ clinical trial
- Accelerating the launch of SHED regenerative medicine products

## KIDS WELL, ALL WELL

### SHED MCB Competed

**Establishment of revenue base**

**Establishment of biosimilar development technology**

- Acquisition of biopharmaceutical development know-how
- Strong sales of GBS-007
- Started development of the 4<sup>th</sup> BS product
- New BS pipeline development

**Accelerating cell therapy products development**

**Focusing on SHED development**

- Accelerating development in overseas in addition to domestic development
- Active investment in human resources and capital
- Accelerating R&D by fund-raising from overseas investors and public research funds such as AMED

**Launching cellular medicine /cell therapy products**

**Aiming to launch the world's first SHED medicine/ therapy by FY2030**

- Steady development progress in Japan and overseas
- Establishment of SHED platform
- Strengthening SHED business activities
- Diverse personnel structure, including experts of cell medicine development and human resources with knowledge of new modalities

### SHED + Human Resource Development

### Maintaining stable revenue of biosimilar business

Founded (2001) to FY 2021      FY 2022      FY 2025 (3 billion yen of sales and 1 billion yen of operating profit)      FY 2030 onward

All for Kids, Kids for All

**KIDS WELL, ALL WELL**



| Term  | Explanation  |
|---|--|
| <b>Cell therapy (Regenerative Medicine)</b> | Cell therapy is the transplantation of human or animal cells to replace or repair damaged tissue. It includes utilizing immune cells in the blood, adipose-derived and born-derived mesenchymal stem cells.  |
| <b>Designer cells</b>                       | Designer cells can enhance therapeutic efficacy and cell directionality for disease sites. They are of interest in the field of diseases without radical cure as a medical treatment of next generation.   |
| <b>Exosome</b>                              | A tiny vesicle created and released from the plasma membrane of various types of cells, especially immune cells, and capable of inducing antigen-specific immune responses. Exosomes are of special interest in the field of medicine with their special ability.  |
| <b>GMP</b>                                  | <b>Good Manufacturing Practice (GMP)</b> is minimum required guidelines that a manufacturer must meet to assure that their products are consistently high in quality and work for their intended use. GMP is a part of a quality system covering the manufacture and testing of pharmaceutical ingredients, foods, pharmaceutical products, diagnostics, and medical devices.  |
| <b>Master Cell Bank (MCB)</b>               | Master Cell Bank (MCB) is cells for medical treatments that are expanded under the constant culture condition and divided into several vials for long frozen storage. Frozen MCB can be expanded again after thawing and utilized for regenerative medicine products as a raw material.  |
| <b>SHED</b>                                 | SHED : <b>S</b> tem cells from <b>H</b> uman <b>E</b> xfoliated <b>D</b> eciduous teeth<br>SHED is a mesenchymal stem cell (MSC) extracted from a dental pulp cavity inside exfoliated deciduous teeth and is easy to differentiate into bone and nerve cells. Especially SHEDs from young donors have shown higher proliferative activity and secretory capacity of various growth factors (particularly neurotrophic factors) compared to stem cells from other tissues. |

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This material includes information on pharmaceutical products and regenerative medicine (or related products), etc., which is being developed or launched. However, this is not intended to promote our products or provide medical advices.