NB: this is a summary translation of the press release original drafted in Japanese for the disclosure required in compliance with the TSE regulations.

# Non-consolidated Financial Results for the Fiscal Year Ended December 31, 2022 [Japanese GAAP]

February 10, 2023

Company name: Oncolys BioPharma Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4588
URL: http://www.oncolys.com
Representative: Yasuo Urata, President & CEO
Contact: Keiji Yoshimura, Vice President
Email: oncolys_information@oncolys.com
Scheduled date of Annual General Meeting of Shareholders: March 29, 2023
Scheduled date of commencing dividend payments: —
Scheduled date of filing annual securities report: March 30, 2023
Availability of supplementary briefing material on financial results: No
Schedule of financial results briefing session: Scheduled (for analysts)

(Amounts of less than one million yen are rounded down.)

## 1. Financial Results for the Fiscal Year Ended December 31, 2022 (January 1, 2022 to December 31, 2022)

(1) Operating Results (% indicates changes from the previous corresponding period.)

| | Net sales | | Operating profit | | Ordinary profit | | Profit | |
|---|---|---|---|---|---|---|---|---|
| Fiscal year ended | Million yen | % | Million yen | % | Million yen | % | Million yen | % |
| December 31, 2022 | 976 | 51.9 | (1,204) | - | (1,163) | - | (1,148) | - |
| December 31, 2021 | 642 | 104.5 | (1,454) | - | (1,500) | - | (1,615) | - |

| | Basic earnings per share | Diluted earnings per share | Rate of return on equity | Ordinary profit to total assets | Operating profit to net sales |
|---|---|---|---|---|---|
| Fiscal year ended | Yen | Yen | % | % | % |
| December 31, 2022 | (66.31) | - | (40.0) | (33.5) | - |
| December 31, 2021 | (95.50) | - | (57.9) | (42.3) | - |

(Reference) Equity in earnings of affiliates: Fiscal year ended December 31, 2022: ¥- million
Fiscal year ended December 31, 2021: ¥- million

(2) Financial Position

| | Total assets | Net assets | Equity ratio | Net assets per share |
|---|---|---|---|---|
| | Million yen | Million yen | % | Yen |
| As of December 31, 2022 | 2,650 | 2,159 | 81.2 | 124.20 |
| As of December 31, 2021 | 4,291 | 3,593 | 83.6 | 206.86 |

(Reference) Equity: As of December 31, 2022: ¥2,151 million
As of December 31, 2021: ¥3,586 million

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(3) Cash Flows

| | Cash flows from operating activities | Cash flows from investing activities | Cash flows from financing activities | Cash and cash equivalents at end of period |
|---|---|---|---|---|
| Fiscal year ended | Million yen | Million yen | Million yen | Million yen |
| December 31, 2022 | (1,717) | 20 | (113) | 1,466 |
| December 31, 2021 | (1,741) | (0) | 3,091 | 3,209 |

**2. Dividends**

| | Annual dividends | | | | | Total dividends | Payout ratio | Dividends to net assets |
|---|---|---|---|---|---|---|---|---|
| | 1st quarter-end | 2nd quarter-end | 3rd quarter-end | Year-end | Total | | | |
| | Yen | Yen | Yen | Yen | Yen | Million yen | % | % |
| Fiscal year ended December 31, 2021 | - | 0.00 | - | 0.00 | 0.00 | - | - | - |
| Fiscal year ended December 31, 2022 | - | 0.00 | - | 0.00 | 0.00 | - | - | - |
| Fiscal year ending December 31, 2023 (Forecast) | - | 0.00 | - | 0.00 | 0.00 | | - | |

**3. Financial Results Forecast for the Fiscal Year Ending December 31, 2023 (January 1, 2023 to December 31, 2023)**

Financial results forecast is not disclosed due to the difficulty of making reasonable estimates. For details, please see "1. Overview of Business Results, etc. (4) Future Outlook" on page 3 of the supplementary material.

*** Notes:**

(1) Changes in accounting policies, changes in accounting estimates and retrospective restatement
1) Changes in accounting policies due to the revision of accounting standards: Yes
2) Changes in accounting policies other than 1) above: No
3) Changes in accounting estimates: No
4) Retrospective restatement: No
(Note) For details, please see "4. Financial Statements and Primary Notes (6) Notes to Financial Statements (Changes in accounting policies)" on page 18 of the supplementary material.

(2) Total number of issued shares (common shares)
1) Total number of issued shares at the end of the period (including treasury shares):
December 31, 2022: 17,405,200 shares
December 31, 2021: 17,405,200 shares

2) Total number of treasury shares at the end of the period:
December 31, 2022: 82,238 shares
December 31, 2021: 68,494 shares

3) Average number of shares during the period:
Fiscal year ended December 31, 2022: 17,327,407 shares
Fiscal year ended December 31, 2021: 16,915,148 shares

<u>* These financial results are outside the scope of audit by certified public accountants or an audit corporation.</u>

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* Explanation of the proper use of financial results forecast and other notes

(Note regarding forward-looking statements, etc.)

The earnings forecasts and other forward-looking statements herein are based on information available to the Company at the time of the release of these materials and certain assumptions deemed reasonable, and do not represent a commitment from the Company that they will be achieved. In addition, actual financial results, etc. may differ significantly due to a wide range of factors. For the assumptions used in forecasting financial results and notes regarding the use of financial forecasts, please see "1. Overview of Business Results, etc. (4) Future Outlook" on page 3 of the supplementary material.

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# 1. Overview of Business Results, etc.

## (1) Overview of Business Results for the Fiscal Year Under Review

The Japanese economy during the fiscal year ended December 31, 2022 showed signs of a return to its previous levels of economic activity as the rate of severe cases of COVID-19 declined. On the other hand, with the energy crunch caused by Russia's invasion of Ukraine and the rapid depreciation of the yen due to the raised policy interest rates in the U.S. and Europe, the volatile situation both in Japan and overseas seems likely to continue.

Under these circumstances, the Company has been pursuing a vision of "Dedicating power to future cancer treatments, and leaving our footprint in the history of cancer treatment through those achievements," thus striving to increase managerial efficiency and actively expand research, development and licensing activities.

In particular, the Company is promoting research, development, and licensing activities with a focus on Telomelysin (OBP-301) virotherapy for cancer. In addition, concerning OBP-601 (Censavudine), a nucleoside reverse transcriptase inhibitor, Transposon Therapeutics, Inc. (hereinafter "Transposon") is conducting clinical trials at its own full expense based on a license agreement.

For details of the Company's activities, please refer to "5. Supplemental Information (1) Research and development activities."

For the fiscal year ended December 31, 2022, net sales were ¥976,182 thousand (net sales of ¥642,494 thousand in the previous fiscal year), and operating loss was ¥1,204,506 thousand (operating loss of ¥1,454,554 thousand in the previous fiscal year). In addition, the Company recorded interest income of ¥587 thousand, foreign exchange gains of ¥62,639 thousand, and other items as non-operating income, and interest expenses of ¥3,945 thousand, amortization of restricted stock remuneration of ¥17,793 thousand, and other items as non-operating expenses. Ordinary loss was ¥1,163,008 thousand (ordinary loss of ¥1,500,888 thousand in the previous fiscal year). Extraordinary profit of ¥21,406 thousand was recorded by selling the convertible bonds of Unleash Immuno Oncolytics, Inc. (Missouri, U.S.; hereinafter "Unleash") to Unleash, and an impairment loss of ¥4,403 thousand on the Company's capital investment in TelomeScan, including analytical equipment, was recorded as extraordinary loss. As a result, net loss was ¥1,148,938 thousand (net loss of ¥1,615,439 thousand in the previous fiscal year).

## (2) Overview of Financial Position for the Fiscal Year Under Review

### 1) Status of Assets, Liabilities and Net Assets

Assets at the end of the fiscal year under review were ¥2,650,959 thousand (38.2% decrease compared with the end of the previous fiscal year), owing partly to a decrease in cash and deposits. Liabilities were ¥491,690 thousand (29.5% decrease compared with the end of the previous fiscal year), owing partly to repayments of long-term loans payable and a decrease in accounts payable - other. Net assets were ¥2,159,269 thousand (39.9% decrease compared with the end of the previous fiscal year), owing to capital increase through issuance of new shares, loss incurred and other factors.

### 2) Status of Cash Flows

Cash and cash equivalents at the end of the fiscal year under review were ¥1,466,201 thousand (45.7% decrease compared with the end of the previous fiscal year). Cash flows for the fiscal year under review were as follows.

(Cash flows from operating activities)

Net cash flows used in operating activities were ¥1,717,135 thousand (a cash outflow of ¥1,741,827 thousand in the previous fiscal year). This is primarily attributable to loss before income taxes of ¥1,146,005

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thousand, share-based remuneration expenses of ¥58,134 thousand, impairment losses of ¥4,403 thousand, a decrease in notes and accounts receivable - trade of ¥352,148 thousand, an increase in advance payments - other of ¥272,301 thousand and a decrease in accounts payable - other of ¥45,371 thousand.

(Cash flows from investing activities)

Net cash flows provided by investing activities were ¥20,117 thousand (a cash outflow of ¥942 thousand in the previous fiscal year). This is primarily attributable to sale of bonds of ¥21,406 thousand and purchase of property, plant and equipment of ¥1,358 thousand.

(Cash flows from financing activities)

Net cash flows used in financing activities were ¥113,830 thousand (a cash inflow of ¥3,091,384 thousand in the previous fiscal year). This is primarily attributable to repayments of long-term loans payable of ¥111,104 thousand and repayments of lease obligations of ¥2,667 thousand.

(3) Overview of Cash Flows for the Fiscal Year Under Review

| | Fiscal year ended December 31, 2020 | Fiscal year ended December 31, 2021 | Fiscal year ended December 31, 2022 |
|---|---|---|---|
| Equity ratio (%) | 71.4 | 83.6 | 81.2 |
| Equity ratio based on fair value (%) | 786.2 | 213.3 | 344.4 |
| Interest-bearing liabilities to cash flows (Note 4) | — | — | — |
| Interest coverage ratio (Note 4) | — | — | — |

Equity ratio: Equity/Total assets

Equity ratio based on fair value: Total market value of shares/Total assets

Interest-bearing liabilities to cash flows: Interest-bearing liabilities /Cash flows

Interest coverage ratio: Cash flows/Interest payments

(Note 1) Total market value of shares was calculated by multiplying the closing price on the fiscal year-end date by the number of outstanding shares on the fiscal year-end date (excluding treasury shares).

(Note 2) Operating cash flows are used as cash flows.

(Note 3) Interest-bearing liabilities include all liabilities recorded on the balance sheets for which interests are paid.

(Note 4) Figures are not presented as operating cash flows were negative.

(4) Future Outlook

The Company still has a small stable revenue base, and our financial results fluctuate greatly depending on contractual lump-sum payments from the conclusion of new contracts and milestone revenue payments generated from licensees achieving events. There is also a risk that disclosing our full-year earnings forecast for the fiscal year ending December 31, 2023 could affect our negotiations on economic terms for the Telomelysin domestic distribution partnership agreement planned for 2023, as well as our negotiations on terms for the Telomelysin collaborative research with a major pharmaceutical company in the United States that markets an immune checkpoint inhibitor.

For these reasons, we believe that it is difficult to calculate an appropriate and reasonable figure for the earnings forecast at this time due to the many undetermined factors that will affect our business performance, and therefore, we refrain from disclosing the forecast. In addition, since the Company manages its performance annually, the Company omits the description of its earnings forecasts for the second quarter (cumulative).

(5) Basic Policy on Profit Distribution and Dividends for the Fiscal Year Under Review and Next Fiscal Year

As a research and development based venture, the Company has focused on upfront investments of business capital, etc., and has yet to distribute profits. However, the Company recognizes the return of profits to

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shareholders to be an important issue for management and will determine its dividend policy that take the operating results of each fiscal year into account, while considering further strengthening of the management foundation and the enhancement of internal reserves in preparation for further proactive business development. In accordance with this basic policy, dividend distributions are not scheduled for the fiscal year under review or the next fiscal year.

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## 2. Management Policies

### (1) Basic Policy on Management

The Company conducts a research- and development-oriented business as a biotech company for drug discovery and promotes the development and commercialization of novel drugs for cancer virotherapy, drugs for the treatment of serious infectious diseases and other drugs. In particular, we aim to grow as a virus drug discovery company focusing on the field of severe viral infections with our main business areas of the oncolytic virus Telomelysin and the next-generation Telomelysin OBP-702, as well as OBP-2011 for the treatment of COVID-19. Furthermore, OBP-601 (Censavudine), which has been developed as a treatment for HIV infection, is being developed by Transposon Therapeutics Inc. (hereinafter "Transposon") under license as a treatment for intractable neurological diseases.

Until now, the Company's business model has been to develop drug pipelines up to the initial clinical trial stage, and then license the pipelines to pharmaceutical companies for further development and marketing in exchange for contractual lump-sum payments, milestone revenue, royalty revenue, etc. Going forward, however, in addition to the license-type business model described above, the Company will consider developing the business of some of its pipelines according to a "hybrid" business model that would combine the license-type business model with the business model of a pharmaceutical company, in which we obtain the required manufacturing and sale approvals by ourselves.

The basic policy of the Company is to provide essential drug discovery services such that "without Oncolys, there will be trouble for the medical field, and thus the patients," and the Company will contribute to early solutions to the challenges faced by the medical field.

### (2) Target Business Indicators

The Company is a research- and development-based biotech company involved in drug discovery, and profits are typically expected to increase when pipelines that are currently in development are placed on the market and we begin receiving commercial drug formulation and supply revenues and royalty revenues from license agreements and marketing partners. Therefore, the Company considers that its research and development expenses necessary to obtain Proof of Concept (POC) in the initial clinical trials, which is a measure of the product value of the pipeline, are an important business indicator. At the present stage, while striving to maximize the value of pipelines for expanding contractual lump-sum payments from licensees and marketing agreement partners and milestone revenue and reducing financial risks, the Company aims to achieve early-stage stability and profitability.

### (3) Medium- to Long-term Management Strategies

The basic strategy of the Company involves a fabless management model utilizing outsourcing in order to realize efficient progress from pre-clinical to clinical trials, with focus placed on hiring and cultivating personnel specializing in project management of drug discovery research and development.

By maximizing the value of our pipeline by achieving rapid progression to the next stage in development, the Company is able to conclude licensing agreements and marketing agreements with major pharmaceutical companies and biotech companies on better conditions.

The Company intends to develop its business in a "hybrid" fashion. Depending on the status of each pipeline and the target region, the Company would choose between a license-type business model in which the Company earns contractual payments and generates royalty revenues after products are launched in the market, and a pharmaceutical company-type business model in which the Company earns revenues by obtaining its own manufacturing and sales approval and supplying commercial drug formulations to its marketing partners. Going forward, the Company will continue to work on rapid progression to the next stages in development of pipelines, and endeavor to construct a foundation of continuous profit by implementing revenue models from multiple pipelines.

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(4) Issues to be Addressed

The following important issues are initiated in the organizational strategy of the Company.

a. Promoting the corporate philosophy

The vision of the Company is to "dedicate its power to future cancer treatments and leave its footprint in the history of cancer treatment through those achievements." We are on an endless quest for medical "innovation." To this end, we spare no efforts in our diligent studies of the medical sciences. One could say we are on an adventure to accomplish big things with a small number of people. We aim to challenge ourselves in projects that big companies cannot. We are focused on how many lives we can save, rather than on how much profit can be made, and we believe this mindset will bring us profit in turn. We share this mindset not only with management and employees, but also with our shareholders. We commit ourselves to transparency in management and regular information disclosure. We aspire to contribute to society, and fully comply with all laws and regulations governing our company's behavior. We consider it important for our management to promote our corporate philosophy among our officers and employees and build an organization that flexibly and enthusiastically executes management strategies based on this corporate philosophy. To this end, we have formulated a code of conduct which embodies this corporate philosophy, and together with instructing officers and employees to comply with this code of conduct, we proactively create opportunities for top management to speak to our officers and employees about our corporate philosophy. On top of that, we are building an organization that places primary importance on the unified sharing of information by the research and development department and business development department. In addition, the management department that manages internal resources is constantly aware of the will of our stakeholders and ensures thorough compliance. Furthermore, the internal audit department serves to enhance monitoring functions, starting with promotion of the corporate philosophy and the code of conduct.

b. Securing and cultivating personnel

The personal growth of each officer and employee is an essential element to the growth of the Company. In order to realize this, the Company actively promotes the recruitment and cultivation of personnel. In particular, as the Company's research, development and business activities are conducted both domestically and internationally, it is important to cultivate human resources with English skills and an international perspective. Utilizing internal and external networks, the Company seeks to recruit personnel who have reliable technique, abilities, and ambitions to grow, in addition to cultivating personnel through OJT and various training programs to enhance the team structure. The Company also endeavors to improve financial results assessments and share-based remuneration systems in order to maximize the speed and quality of business operations.

c. Strengthening research and development structures

The research and development of the Company covers the whole process from the search and invention of prospective pharmaceuticals and detection drugs to pre-clinical trials and initial clinical trials (i.e., proof of concept), and the main role of the Company is to act as a bridge between the pre-clinical and clinical stages (i.e., translational research). Therefore, it is an important issue to secure and cultivate personnel who take responsibility as project leaders engaging primarily in planning and progress management for research and development. The Company has its research and development system both in Japan and overseas. The Company strives to enhance collaboration with the clinical development department of a wholly-owned subsidiary Oncolys USA Inc. (hereinafter "OUS"). Furthermore, along with incorporating advanced technologies and improving technological levels through joint research and development with global medical and research institutions, the Company actively utilizes outsourcing partners and endeavors to construct low-cost and high-level research and development structures.

d. Strengthening business development department

The Company defines its business fields as the field of virotherapy for cancer using genetically modified virus formulations and the field of serious infectious diseases, aiming for the commercialization of exceedingly

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unique virus drug discovery for this industry. Therefore, the Company will secure and cultivate talent that possesses both business skills and abundant scientific knowledge and strengthen its network with pharmaceutical companies around the world. Furthermore, by enhancing collaboration with our subsidiary in the United States, Oncolys USA, the Company aims to generate numerous joint development and licensing opportunities with pharmaceutical companies overseas and construct business development structures that can contribute to increasing its cash flows.

e. Outsourcing strategies

In the Company business that revolves around outsourcing, efficiency improvement is an important issue. In order to strengthen relationships with outsourcing companies such as CROs (Contract Research Organizations) and CMOs (Contract Manufacturing Organizations) in securing necessary and sufficient research, development, and manufacturing capabilities, the Company instructs the whole organization to ensure a dedicated contact system through making regular visits, etc. Also, in order to ensure ideal outsourcing structures at all times, the Company will search secondary contractors and build relationships so that operations do not become dependent on any specific company in each business field.

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## 3. Basic Stance Concerning Choice of Accounting Standards

Since the Company has not prepared consolidated financial statements, the burden of establishing a system for preparing financial statements based on international accounting standards has been taken into consideration, and the financial statements have been prepared based on Japanese standards.

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## 4. Financial Statements and Primary Notes

### (1) Balance Sheets

(Thousand yen)

| | As of December 31, 2021 | As of December 31, 2022 |
|---|---|---|
| Assets | | |
| Current assets | | |
| Cash and deposits | 3,454,714 | 1,711,280 |
| Accounts receivable – trade | 352,148 | – |
| Finished goods | 8,434 | 8,434 |
| Work in process | – | 12,666 |
| Supplies | 3,222 | 3,149 |
| Advance payments – other | 234,014 | 506,316 |
| Prepaid expenses | 120,977 | 47,970 |
| Short-term loans receivable from subsidiaries and associates | – | 39,813 |
| Accounts receivable – other | 4,179 | 174,310 |
| Income taxes refund receivable | – | 28,299 |
| Consumption taxes receivable | 20,304 | 75,982 |
| Advances paid | – | 29 |
| Other | 12 | 501 |
| Total current assets | 4,198,008 | 2,608,754 |
| Non-current assets | | |
| Property, plant and equipment | | |
| Buildings | 2,794 | 2,794 |
| Accumulated depreciation | (2,794) | (2,794) |
| Buildings, net | – | – |
| Tools, furniture and fixtures | 65,024 | 65,939 |
| Accumulated depreciation | (65,024) | (65,939) |
| Tools, furniture and fixtures, net | – | – |
| Total property, plant and equipment | – | – |
| Investments and other assets | | |
| Shares of subsidiaries and associates | 20,936 | 20,936 |
| Investments in capital | 100 | 100 |
| Long-term loans receivable from subsidiaries and associates | 34,503 | – |
| Lease and guarantee deposits | 21,220 | 21,149 |
| Long-term prepaid expenses | 17,090 | – |
| Other | 19 | 19 |
| Total investments and other assets | 93,868 | 42,204 |
| Total non-current assets | 93,868 | 42,204 |
| Total assets | 4,291,876 | 2,650,959 |

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(Thousand yen)

| | As of December 31, 2021 | As of December 31, 2022 |
|---|---|---|
| Liabilities | | |
| Current liabilities | | |
| Short-term loans payable | 238,880 | 227,776 |
| Lease obligations | 2,674 | 3,581 |
| Accounts payable – other | 106,247 | 60,858 |
| Accrued expenses | 16,846 | 17,099 |
| Income taxes payable | 59,242 | 2,931 |
| Deposits received | 6,320 | 9,392 |
| Total current liabilities | 430,211 | 321,639 |
| Non-current liabilities | | |
| Long-term loans payable | 255,544 | 155,544 |
| Lease obligations | 6,372 | 6,758 |
| Provision for retirement benefits | 5,756 | 7,748 |
| Total non-current liabilities | 267,673 | 170,051 |
| Total liabilities | 697,884 | 491,690 |
| Net assets | | |
| Shareholders' equity | | |
| Capital stock | 9,039,516 | 3,000,000 |
| Capital surplus | | |
| Legal capital surplus | 9,031,904 | 586,425 |
| Other capital surplus | 31,740 | – |
| Total capital surpluses | 9,063,645 | 586,425 |
| Retained earnings | | |
| Other retained earnings | | |
| Retained earnings brought forward | (14,516,735) | (1,434,694) |
| Total retained earnings | (14,516,735) | (1,434,694) |
| Treasury shares | (113) | (142) |
| Total shareholders' equity | 3,586,312 | 2,151,589 |
| Share acquisition rights | 7,680 | 7,680 |
| Total net assets | 3,593,992 | 2,159,269 |
| Total liabilities and net assets | 4,291,876 | 2,650,959 |

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(2) Statements of Income

(Thousand yen)

| | For the fiscal year ended December 31, 2021 | For the fiscal year ended December 31, 2022 |
|---|---|---|
| Net sales | 642,494 | 976,182 |
| Cost of sales | | |
| Cost of service | 443,690 | 637,695 |
| Beginning finished goods | 8,434 | 8,434 |
| Total | 8,434 | 8,434 |
| Ending finished goods | 8,434 | 8,434 |
| Gross profit | 198,803 | 338,487 |
| Selling, general and administrative expenses | 1,653,357 | 1,542,993 |
| Operating loss | (1,454,554) | (1,204,506) |
| Non-operating income | | |
| Interest income | 494 | 587 |
| Dividend income | 3 | 3 |
| Foreign exchange gains | 37,369 | 62,639 |
| Other | 776 | 37 |
| Total non-operating income | 38,643 | 63,267 |
| Non-operating expenses | | |
| Interest expenses | 4,169 | 3,945 |
| Amortization of restricted stock remuneration | 68,525 | 17,793 |
| Share acquisition rights issuance costs | 413 | – |
| Share issuance costs | 11,652 | 30 |
| Other | 218 | 0 |
| Total non-operating expenses | 84,977 | 21,769 |
| Ordinary loss | (1,500,888) | (1,163,008) |
| Extraordinary income | | |
| Gain on sale of bonds | – | 21,406 |
| Total extraordinary income | – | 21,406 |
| Extraordinary losses | | |
| Impairment loss | 19,845 | 4,403 |
| Loss on valuation of shares of subsidiaries and associates | 90,980 | – |
| Total extraordinary losses | 110,825 | 4,403 |
| Loss before income taxes | (1,611,714) | (1,146,005) |
| Income taxes – current | 3,725 | 2,932 |
| Total income taxes | 3,725 | 2,932 |
| Loss | (1,615,439) | (1,148,938) |

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(3) Detailed Schedule of Manufacturing Cost

| | | For the fiscal year ended December 31, 2021 | | For the fiscal year ended December 31, 2022 | |
|---|---|---|---|---|---|
| Category | Note No. | Amount (Thousand yen) | Composition (%) | Amount (Thousand yen) | Composition (%) |
| I. Material cost | | – | | – | |
| II. Labor cost | | – | | – | |
| III. Expenses | | – | | 12,666 | 100.0 |
| Total manufacturing cost | | – | | 12,666 | 100.0 |
| Beginning work in process | | – | | – | |
| Other account received | | – | | – | |
| Total | | – | | 12,666 | |
| Ending work in process | | – | | 12,666 | |
| Transfer to other account | | – | | – | |
| Cost of products manufactured | | – | | – | |

Calculation method of costs

Costs calculation methods vary based on the calculation of individual product costs.

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(4) Statements of Changes in Equity

For the fiscal year ended December 31, 2021

(Thousand yen)

| | Shareholders' equity | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Capital stock | Capital surplus | | | Retained earnings | | Treasury shares | Total shareholders' equity |
| | | Legal capital surplus | Other capital surplus | Total capital surpluses | Other retained earnings<br>Retained earnings brought forward | Total retained earnings | | |
| Balance at beginning of current period | 7,436,537 | 7,428,925 | 31,740 | 7,460,666 | (12,901,296) | (12,901,296) | (76) | 1,995,830 |
| Cumulative effects of changes in accounting policies | | | | | | | | |
| Restated balance | | | | | | | | |
| Changes of items during period | | | | | | | | |
| Issuance of new shares | 1,602,979 | 1,602,979 | | 1,602,979 | | | | 3,205,958 |
| Capital reduction | | | | | | | | |
| Deficit disposition | | | | | | | | |
| Loss | | | | | (1,615,439) | (1,615,439) | | (1,615,439) |
| Purchase of treasury shares | | | | | | | (36) | (36) |
| Net changes of items other than shareholders' equity | | | | | | | | |
| Total changes of items during period | 1,602,979 | 1,602,979 | – | 1,602,979 | (1, 615,439) | (1, 615,439) | (36) | 1,590,482 |
| Balance at end of current period | 9,039,516 | 9,031,904 | 31,740 | 9,063,645 | (14,516,735) | (14,516,735) | (113) | 3,586,312 |

| | Valuation and translation adjustments | | Share acquisition rights | Total net assets |
|---|---|---|---|---|
| | Valuation difference on available-for-sale securities | Total valuation and translation adjustments | | |
| Balance at beginning of current period | (254) | (254) | 7,750 | 2,003,325 |
| Cumulative effects of changes in accounting policies | | | | |
| Restated balance | | | | |
| Changes of items during period | | | | |
| Issuance of new shares | | | | 3,205,958 |
| Capital reduction | | | | |
| Deficit disposition | | | | |
| Loss | | | | (1,615,439) |
| Purchase of treasury shares | | | | (36) |
| Net changes of items other than shareholders' equity | 254 | 254 | (70) | 184 |
| Total changes of items during period | 254 | 254 | (70) | 1,590,666 |
| Balance at end of current period | – | – | 7,680 | 3,593,992 |

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For the fiscal year ended December 31, 2022

(Thousand yen)

| | Shareholders' equity | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Capital stock | Capital surplus | | | Retained earnings | | Treasury shares | Total shareholders' equity |
| | | Legal capital surplus | Other capital surplus | Total capital surpluses | Other retained earnings<br>Retained earnings brought forward | Total retained earnings | | |
| Balance at beginning of current period | 9,039,516 | 9,031,904 | 31,740 | 9,063,645 | (14,516,735) | (14,516,735) | (113) | 3,586,312 |
| Cumulative effects of changes in accounting policies | | | | | (285,756) | (285,756) | | (285,756) |
| Restated balance | 9,039,516 | 9,031,904 | 31,740 | 9,063,645 | (14,802,491) | (14,802,491) | (113) | 3,300,556 |
| Changes of items during period | | | | | | | | |
| Issuance of new shares | – | – | | – | | | | – |
| Capital reduction | (6,039,516) | (8,445,478) | 14,484,995 | 6,039,516 | | | | – |
| Deficit disposition | | | (14,516,735) | (14,516,735) | 14,516,735 | 14,516,735 | | – |
| Loss | | | | | (1,148,938) | (1,148,938) | | (1,148,938) |
| Purchase of treasury shares | | | | | | | (28) | (28) |
| Net changes of items other than shareholders' equity | – | – | – | – | | – | | – |
| Total changes of items during period | (6,039,516) | (8,445,478) | (31,740) | (8,477,219) | 13,367,797 | 13,367,797 | (28) | (1,148,966) |
| Balance at end of current period | 3,000,000 | 586,425 | – | 586,425 | (1,434,694) | (1,434,694) | (142) | 2,151,589 |

| | Valuation and translation adjustments | | Share acquisition rights | Total net assets |
|---|---|---|---|---|
| | Valuation difference on available-for-sale securities | Total valuation and translation adjustments | | |
| Balance at beginning of current period | – | – | 7,680 | 3,593,992 |
| Cumulative effects of changes in accounting policies | | | | (285,756) |
| Restated balance | | | 7,680 | 3,308,236 |
| Changes of items during period | | | | |
| Issuance of new shares | | | | – |
| Capital reduction | | | | – |
| Deficit disposition | | | | – |
| Loss | | | | (1,148,938) |
| Purchase of treasury shares | | | | (28) |
| Net changes of items other than shareholders' equity | – | – | – | – |
| Total changes of items during period | – | – | – | (1,148,966) |
| Balance at end of current period | – | – | 7,680 | 2,159,269 |

TRANSLATION

(5) Statements of Cash Flows

(Thousand yen)

| | For the fiscal year ended December 31, 2021 | For the fiscal year ended December 31, 2022 |
|---|---|---|
| Cash flows from operating activities | | |
| Loss before income taxes | (1,611,714) | (1,146,005) |
| Depreciation | 6,486 | 914 |
| Impairment loss | 19,845 | 4,403 |
| Loss on valuation of shares of subsidiaries and associates | 90,980 | – |
| Amortization of restricted stock remuneration | 68,525 | 17,793 |
| Gain on sale of bonds | – | (21,406) |
| Share-based remuneration expenses | 208,951 | 58,134 |
| Increase (decrease) in provision for retirement benefits | 836 | 1,992 |
| Interest and dividend income | (497) | (590) |
| Interest expenses | 4,169 | 3,945 |
| Foreign exchange losses (gains) | (41,632) | (72,723) |
| Decrease (increase) in notes and accounts receivable – trade | (281,549) | 352,148 |
| Decrease (increase) in inventories | (1,183) | (12,593) |
| Decrease (increase) in prepaid expenses | (32,606) | 14,168 |
| Decrease (increase) in accounts receivable – other | (2,538) | (198,392) |
| Decrease (increase) in consumption taxes refund receivable | 75,450 | (55,677) |
| Increase (decrease) in accrued consumption taxes | – | – |
| Decrease (increase) in advance payments – other | (190,659) | (272,301) |
| Increase (decrease) in accounts payable – other | (100,336) | (45,371) |
| Increase (decrease) in contract liabilities | – | (285,756) |
| Other, net | 53,158 | (54,940) |
| Subtotal | (1,734,314) | (1,712,259) |
| Interest and dividend income received | 407 | 553 |
| Interest expenses paid | (4,194) | (3,962) |
| Income taxes paid | (3,725) | (1,466) |
| Net cash provided by (used in) operating activities | (1,741,827) | (1,717,135) |
| Cash flows from investing activities | | |
| Proceeds from sale of investment securities | 486 | – |
| Payments into time deposits | (1) | (1) |
| Proceeds from sale of bonds | – | 21,406 |
| Purchase of property, plant and equipment | (1,437) | (1,358) |
| Payments for lease and guarantee deposits | (71) | – |
| Proceeds from refund of lease and guarantee deposits | 80 | 71 |
| Net cash provided by (used in) investing activities | (942) | 20,117 |
| Cash flows from financing activities | | |
| Proceeds from long-term loans payable | 100,000 | 100,000 |
| Net increase (decrease) in short-term loans payable | – | (100,000) |
| Repayments of long-term loans payable | (122,232) | (111,104) |
| Repayments of lease obligations | (2,609) | (2,667) |
| Proceeds from issuance of common shares | 3,085,424 | – |
| Proceeds from issuance of share acquisition rights | 42,902 | – |
| Purchase of treasury shares | (36) | (28) |
| Other payments | (12,065) | (30) |
| Net cash provided by (used in) financing activities | 3,091,384 | (113,830) |
| Effect of exchange rate change on cash and cash equivalents | 38,171 | 67,413 |
| Net increase (decrease) in cash and cash equivalents | 1,386,785 | (1,743,434) |
| Cash and cash equivalents at beginning of year | 1,822,850 | 3,209,635 |
| Cash and cash equivalents at end of period | 3,209,635 | 1,466,201 |

(6) Notes to Financial Statements

(Notes on going concern assumption)

There is no relevant information.

(Significant accounting policies)

1. Valuation standards and methods for securities

(1) Shares in subsidiaries and associates

Stated at cost using the moving-average method.

(2) Other securities

Securities other than shares, etc. that do not have a market price

Stated at fair value (Any valuation differences are directly charged or credited to net assets in full, and cost of securities sold is calculated by the moving average method.)

Shares, etc. that do not have a market price

Stated at cost using the moving-average method.

2. Valuation standards and methods of inventories

Finished goods

Stated at cost using the specific indentation method (The balance sheet value is calculated using the method of reducing book value based on decreased profitability.)

Work in process

Stated at cost using the specific indentation method (The balance sheet value is calculated using the method of reducing book value based on decreased profitability.)

Supplies

Stated at cost using the specific indentation method (The balance sheet value is calculated using the method of reducing book value based on decreased profitability.)

3. Depreciation and amortization methods for non-current assets

(1) Property, plant and equipment (excluding leased assets)

Buildings, and attached facilities and structures acquired on or after April 1, 2016 are depreciated under the straight-line method, and other property, plant and equipment are depreciated under the declining-balance method.

Major useful lives are as follows:

| | |
|---|---|
| Buildings | 3 – 15 years |
| Tools, furniture and fixtures | 3 – 8 years |

(2) Intangible assets (excluding leased assets)

Straight-line method

Software for internal use is depreciated under the straight-line method based on their estimated useful lives (5 years).

(3) Leased assets

Depreciated over respective lease periods by the straight-line method without residual value.

4. Accounting method for deferred assets

Share issuance costs

Charged to expenses when incurred.

5. Standard for translation of foreign-currency-denominated assets or liabilities into Japanese yen

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Foreign currency denominated money claims and liabilities are translated into Japanese yen at the spot exchange rates on the closing date and any conversion difference is treated as profit or loss.

6. Accounting standards for reserves

(1) Allowance for doubtful accounts

To prepare for potential credit losses on receivables, an estimated uncollectible amount is recorded at the amount calculated based on the historical rate of credit loss with respect to normal receivables, and based on the recoverability of individual cases for specified receivables such as doubtful receivables that may not be recoverable.

(2) Provision for retirement benefits

To prepare for the payment of retirement benefits to employees, a simplified method is adopted whereby an amount to be required at year-end for voluntary termination is regarded as a retirement benefit obligation in calculating provision for retirement benefits and retirement benefit expenses.

7. Capital covered by statements of cash flows

Capital as used in the statements of cash flows comprises cash on hand, deposits available for withdrawal as needed, and short-term investments due for redemption within three months from the date of acquisition, which are easily convertible to cash and are subject to minimal risk of fluctuation in value.

8. Other important matters serving as the basis for preparing financial statements

Accounting principles and procedures adopted when the provisions of relevant accounting standards, etc. are not clear

Restricted stock compensation plan

Based on the Company's restricted stock compensation plan, compensation paid to Directors and employees of the Company is accounted for as expenses over the applicable period of service.

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(Changes in accounting policies)

(Adoption of Accounting Standard for Revenue Recognition)

The Company has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020; hereinafter "Revenue Recognition Standard"), etc. from the beginning of the fiscal year under review. The Company recognizes revenue when control of a promised good or service is transferred to a customer in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods and services. Previously, the Company had recognized the total amount of development cooperation money received from joint development partners as income and cost of sales at the time of billing. With the application of the Revenue Recognition Standard, the Company adopted the method of recognizing only the development expenses at the net amount. In addition, the Company had previously recognized the revenues from a contractual lump-sum payment, the milestone revenue payment, sales of investigational drugs, and manufacturing method development contributions based on an out-licensing contract at the time of the confirmation of billing or at a specific point in time during the acceptance inspection based on the license agreement. However, for the fiscal year under review, the Company adopted the method of recognizing the revenue over a certain period of time according to the fulfillment of performance obligations related to the contract if any of the performance obligation related to the contractual lump-sum payment, the milestone revenue payment, sales of investigational drugs, and manufacturing method development contributions based on an out-licensing contract is not satisfied at a specific point in time.

The Company applies the Revenue Recognition Standard, etc. in accordance with the transitional treatment provided for in the proviso to Paragraph 86 of the Revenue Recognition Standard. The cumulative impact of retrospectively applying the new accounting policies to prior periods is adjusted to retained earnings brought forward at the beginning of the fiscal year under review, with the new accounting policies applied from the beginning balance. However, the Company applies the method provided for in Paragraph 86 of the Revenue Recognition Standard, and does not apply the new accounting policies retrospectively to contracts for which substantially all revenue amounts had been recognized prior to the beginning of the fiscal year under review in accordance with the previous treatment. In addition, applying the method stipulated in proviso (1) to Paragraph 86 of the Revenue Recognition Standard, contract modifications that occurred prior to the beginning of the fiscal year under review were accounted for based on the terms of the contract after reflecting all contract modifications, with the cumulative impact adjusted to retained earnings brought forward at the beginning of the fiscal year under review.

As a result of this change, for the fiscal year ended December 31, 2022, in comparison with the case where this accounting policy has not been applied, net sales decreased by ¥7,562 thousand, cost of sales decreased by ¥270,541 thousand, selling, general and administrative expenses decreased by ¥22,777 thousand, and operating profit, ordinary profit, and profit before income taxes increased by ¥285,755 thousand, respectively. In addition, the beginning balance of retained earnings brought forward decreased by ¥285,756 thousand.

In accordance with the transitional treatment set forth in Paragraph 89-2 of the Revenue Recognition Standard, figures for the previous period have not been reclassified based on the new presentation method. In accordance with the transitional treatment set forth in Paragraph 89-3 of the Revenue Recognition Standard, information on the disaggregation of revenue from contracts with customers for the cumulative period of the previous fiscal year is not presented.

(Adoption of Accounting standard for Fair Value Measurement)

The Company has applied the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30, July 4, 2019; hereinafter "Fair Value Measurement Standard"), etc. from the beginning of the fiscal year under review, and will prospectively apply the new accounting policies stipulated by the Fair Value Measurement Standard, etc. in accordance with the transitional treatment provided in Paragraph 19 of the Fair Value Measurement Standard and Paragraph 44-2 of the "Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, July 4, 2019). This does not affect the financial statements.

(Notes related to balance sheets)

TRANSLATION

Contingent liabilities

The Company has been billed for costs related to deviations in the manufacturing process by a contract manufacturer in the United States and is currently discussing the details of the claim.

After consulting with outside experts, we have determined that there is no reason to comply with the claim for such expenses, but depending on future developments, there may be an impact on our business performance. Please note that we have not recorded this as an expense at the end of the fiscal year under review because it is extremely difficult to reasonably estimate the impact.

(Notes on significant changes in shareholders' equity)

In accordance with the resolution passed at the Annual General Meeting of Shareholders held on March 30, 2022, the capital reduction became effective on May 31, 2022. Accordingly, capital stock and legal capital surplus have been reduced by ¥6,039,516 thousand and ¥8,445,478 thousand, respectively, and the amounts have been transferred to other capital surplus. As a result, capital stock amounted to ¥3,000,000 thousand and legal capital surplus amounted to ¥586,425 thousand at the end of the fiscal year under review.

(Equity in earnings (losses) of affiliates if equity method is applied)

The affiliated company owned by the Company is omitted because it is an affiliated company with little importance from the profit standards and retained earnings standards.

TRANSLATION

(Revenue recognition)

1. Disaggregation of revenue from contracts with customers

For the fiscal year ended December 31, 2022

(Thousand yen)

| | |
|---|---|
| Goods / Services transferred at a point in time | 63,075 |
| Goods / Services transferred over time | 913,107 |
| Revenue from contracts with customers | 976,182 |
| Revenue from other sources | ― |
| Net sales to outside customers | 976,182 |

(Segment information, etc.)

a. Segment information

The information is omitted, as the Company consists of a single segment of the drug discovery business.

b. Related information

For the fiscal year ended December 31, 2021

1. Information by product and service

- The information is omitted, as the segmentation of product and service is equivalent to the segmentation of reportable segments.
- The information is omitted, as net sales to outside customers in a single product and service segment exceed 90% of net sales on the Statements of Income.

2. Information by geographical area

(1) Net sales

(Thousand yen)

| Japan | U.S. | Other Asia | Total |
|---|---|---|---|
| 318,912 | 35,930 | 287,652 | 642,494 |

(Note) Net sales are classified by country or area, based on the locations of customers.

(2) Property, plant and equipment

There is no relevant information as the Company does not have property, plant and equipment located outside Japan.

3. Information by major customer

(Thousand yen)

| Name of client | Net sales | Related segment |
|---|---|---|
| Company A | 302,707 | Drug discovery business |
| Company B | 287,652 | Drug discovery business |

(Note) The Company refrains from disclosing company names due to confidentiality clauses present in the various contracts held with customers.

TRANSLATION

For the fiscal year ended December 31, 2022

1. Information by product and service
   - The information is omitted, as the segmentation of product and service is equivalent to the segmentation of reportable segments.
   - The information is omitted, as net sales to outside customers in a single product and service segment exceed 90% of net sales on the Statements of Income.

2. Information by geographical area

(1) Net sales

(Thousand yen)

| Japan | U.S. | Other Asia | Total |
|---|---|---|---|
| 950,394 | 25,788 | – | 976,182 |

(Note) Net sales are classified by country or area, based on the locations of customers.

(2) Property, plant and equipment

There is no relevant information as the Company does not have property, plant and equipment located outside Japan.

3. Information by major customer

(Thousand yen)

| Name of client | Net sales | Related segment |
|---|---|---|
| Chugai Pharmaceutical Co., Ltd. | 913,107 | Drug discovery business |
| Okayama University | 37,287 | Drug discovery business |
| Transposon Therapeutics, Inc. | 25,788 | Drug discovery business |

c. Information on impairment losses of non-current assets by reportable segment

The information is omitted, as the Company consists of a single segment of the drug discovery business.

d. Information on amortization amount and unamortized balance of goodwill by reportable segment

The information is omitted, as the Company consists of a single segment of the drug discovery business.

e. Information on gain on bargain purchase by reportable segment

The information is omitted, as the Company consists of a single segment of the drug discovery business.

TRANSLATION

(Per share information)

| | For the fiscal year ended December 31, 2021 | For the fiscal year ended December 31, 2022 |
|---|---|---|
| Net assets per share | ¥206.86 | ¥124.20 |
| Loss per share | ¥(95.50) | ¥(66.31) |

(Notes) 1. Diluted earnings per share are not presented because of the posting of loss per share, although there are residual shares.

2. The basis for the calculation of loss per share is as follows.

| | For the fiscal year ended December 31, 2021 | For the fiscal year ended December 31, 2022 |
|---|---|---|
| Loss per share | | |
| Loss (Thousand yen) | (1,615,439) | (1,148,938) |
| Amount not attributable to common shareholders (Thousand yen) | — | — |
| Loss relating to common shares (Thousand yen) | (1,615,439) | (1,148,938) |
| Average number of shares during the period (shares) | 16,915,148 | 17,327,407 |

(Significant subsequent events)

There is no relevant information.

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## 5. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the twelve months ended December 31, 2022 totaled ¥947,491 thousand for the drug discovery business.

Furthermore, the status of research and development activities during the fiscal year under review is as follows.

(1) Research and development structure

As of December 31, 2022, 19 persons belonged to research and development department, equivalent to 50.0% of the total number of employees.

(2) Research and development and business activities

The Company promoted research and development, and active business activities centered on the following projects.

1) Activities related to Telomelysin (OBP-301) (International Nonproprietary Name: suratadenoturev) virotherapy for cancer

Now that Telomelysin has been granted "SAKIGAKE designation" for regenerative medicine products in Japan and completed enrollment of patients for the "Phase II clinical trial in combination with radiation therapy for esophageal cancer," the Company plans to file for approval in Japan in 2024. On the manufacturing front, we have made progress in viral production development on a commercial manufacturing scale, and discussions are underway with the PMDA to apply for approval. On the business front, we have begun preparing to establish our own manufacturing and sales system, and we have started due diligence and negotiations on terms and conditions for an alliance with several domestic and foreign companies that are candidates to be our marketing partners. In addition, discussions are underway with a major foreign pharmaceutical company that markets immune checkpoint inhibitors for the joint development of Telomelysin in the U.S.

Currently, the following three clinical trials are underway in Japan and overseas, including the clinical trial for which enrollment has been completed:

i) Phase II clinical trial in combination with radiation therapy for esophageal cancer;
ii) Phase II investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for gastric cancer/gastroesophageal junction cancer; and
iii) Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer

Regarding the above i) "Phase II clinical trial in combination with radiation therapy for esophageal cancer," trials are ongoing based on the SAKIGAKE designation of April 2019. Administration to the first patient began in Japan in March 2020, and we confirmed that the target number of patients for this clinical trial was reached in December 2022. Results for the primary endpoint of this trial, the local response rate in esophageal cancer, are expected to be available in the second half of 2023. To date, no serious safety issues have emerged that would require the suspension of this clinical trial.

Regarding the above ii) "Phase II investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for gastric cancer/gastroesophageal junction cancer," administration to the first patient began in May 2019 led by Cornell University in the U.S. In this trial, an evaluation of the efficacy and safety of Telomelysin and pembrolizumab will be performed for the most advanced stage IV patients. Long-term survival has been confirmed in 3 of the 16 patients enrolled so far. This result exceeded the borderline required to demonstrate the efficacy of this trial. Cornell University will therefore complete patient enrollment for this trial by the end of 2022 and compile clinical data. In order to conduct a new investigator-initiated clinical trial for second-line treatment of gastric cancer, we are now in discussions with a pharmaceutical company that markets immune checkpoint inhibitors for the purpose of co-development. We plan to conclude the same agreement in 2023.

In addition to the orphan drug designation for esophageal cancer that we have already obtained in the U.S., we are also working toward obtaining orphan drug designation for gastric cancer in the U.S.

Regarding the above iii) "Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer," NRG Oncology, a leading cancer research group in the U.S., has been leading the trial, and administration to the first patient began in December 2021. This clinical trial is being conducted in six

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facilities with the primary purpose of confirming the safety of using Telomelysin in combination with chemoradiotherapy. Thus far, Telomelysin has been administered to four patients, and there have been no reports of problematic side-effects. Telomelysin has been designated as an orphan drug for esophageal cancer in the U.S., and this clinical trial will be conducted on that basis. Therefore, in addition to being able to consult with the FDA for advice in conducting clinical trials, the Company will be able to receive preferential treatment in the form of grants and tax credits for clinical research expenses. In addition, first-mover rights protection will be granted for seven years after the approval of Telomelysin in the U.S. and market exclusivity will be granted during that period.

In addition to the above, the investigator-initiated trial "Phase I investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for solid tumors" has also concluded. The National Cancer Center Hospital East plans to present the clinical results from a total of 22 patients at the American Association for Cancer Research (AACR) Annual Meeting in the U.S. in April 2023.

2) Activities related to OBP-601 (Censavudine), a nucleoside reverse transcriptase inhibitor

The Company licensed in OBP-601 from Yale University in 2006. From 2010 to 2014, it was licensed to Bristol-Myers Squibb Co. (hereinafter "BMS"), which promoted its development up to the completion of Phase II clinical trials as a treatment drug for HIV infection. The results demonstrated the equivalence of OBP-601 to existing drugs. During the same period, BMS also obtained numerous clinical safety data and results of long-term toxicity studies, including oncogenicity studies, for OBP-601, but the license agreement was terminated due to a change in strategy by BMS to withdraw from the HIV field.

Later on, in June 2020, after research at Brown University (U.S.) drew attention to the phenomenon that OBP-601 had higher brain translocability than other reverse transcriptase inhibitors and that OBP-601 suppressed the expression of retrotransposons, which are responsible for intractable neurological diseases, the Company concluded a new license agreement with Transposon totaling over $300 million primarily for intractable neurological diseases. Transposon achieved its first milestone in November 2020.

Transposon is currently conducting two double-blind Phase IIa clinical trials, one on progressive supranuclear palsy (PSP) and the other on C9-amyotrophic lateral sclerosis (C9-ALS) and frontotemporal degeneration (FTD) at numerous facilities in Europe and the U.S. Administration to the first patient under the clinical trial for PSP began in November 2021, and enrollment of the target number of patients was reached by the end of 2022. Administration to the first patient under the clinical trial for C9-ALS and FTD also began in January 2022. So far, there have been no reports of safety problems that necessitate the termination of the trials.

Transposon plans to report the results of the interim analysis of the Phase IIa clinical trial for PSP to the Company in 2023 and the interim analysis of the Phase IIa clinical trial for C9-ALS and FTD in 2024. The above-mentioned clinical trials on OBP-601 by Transposon have been proceeding entirely at its own expense.

Transposon is a company that was established with the purpose of developing OBP-601. The Company therefore believes that the risk of Transposon suspending the development of OBP-601 due to a change in strategy is low.

3) Activities related to OBP-2011 for the treatment of COVID-19

Based on experimental outcomes, the Company assumes that its OBP-2011 is a nucleocapsid inhibitor, but the specific mechanism has not been clarified yet at this stage. It is speculated that OBP-2011 has a new mechanism that differs from the main mechanisms of polymerase and protease inhibition already approved for the treatment of coronaviruses, and data indicated that its effectiveness is not influenced by such factors as virus mutation. However, it has become necessary to revise the development policy as the hurdle has been raised for obtaining approval for our proposed COVID-19 treatment, at the same time as changes have emerged in the external environment, such as the reduced urgency due to the launch of multiple therapeutic drugs for COVID-19 to the market. Going forward, the Company will proceed with clarifying the detailed mechanism of action for OBP-2011 by conducting collaborative research with Kagoshima University and the National Institute of Infectious Diseases and pursue a framework for joint development with pharmaceutical companies.

4) Activities related to next generation Telomelysin (OBP-702)

OBP-702 is a second-generation virotherapeutic drug with two anti-tumor effects, combining the "oncogene therapy" that carries the powerful cancer suppressor gene p53 in the vector with the "oncolytic functions" of Telomelysin. At present, a research group led by Professor Toshiyoshi Fujiwara of the Department of Gastroenterological Surgery, Transplant, and Surgical Oncology of Okayama University is conducting non-

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clinical trials on OBP-702, which was adopted as a grant program by the Japan Agency for Medical Research and Development (AMED). In particular, in an experiment on gemcitabine-resistant pancreatic cancer cell lines using mouse models, OBP-702, used in combination with PD-L1 antibodies, exhibited stronger anti-tumor effects than either of them administered alone. It is expected that OBP-702 will be developed as a new treatment method for pancreatic cancer and other refractory cancers. Development of OBP-702 will continue within the scope of the AMED grant.

5) Activities related to TelomeScan (OBP-401), a cancer detection drug

Regarding TelomeScan, the Company set up a "Collaborative Research Program on Minimally Invasive Cancer Detection Method Using TelomeScan," in June 2021, with Juntendo University, aimed at establishing a platform for automated detection of live Circulating Tumor Cells (CTC) within the blood of cancer patients. The Company conducted a joint development agreement with K.K. CYBO in March 2022 and is proceeding with the development of automatic detection software using AI technology, aiming to not only reduce the time for processing test results but also improve the sensitivity and specificity of CTC detection and bring this platform to practical use in Japan.

6) Activities related to OBP-801, HDAC inhibitor

Regarding OBP-801, a histone deacetylase (HDAC) inhibitor licensed from Astellas Pharma Inc. in 2009, dose limiting toxicity was observed in Phase I clinical trials targeting solid body cancers in the U.S., making it impossible to escalate the dosage to the presumed effective dose. Therefore, development in the field of cancer has been suspended.

On the other hand, research for application to glaucoma surgery has been carried out at the Department of Ophthalmology of Kyoto Prefectural University of Medicine in the ophthalmic field, which is a new area of indication for OBP-801, revealing that the drug suppresses fibrosis after filtering bleb formation from glaucoma surgery. The research results will be presented at a meeting of the Japanese Ophthalmological Society in April 2023. Going forward, there is hope for development in the form of eye drops.

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The development status of pipeline products is as follows.

| Product | Indication | Combination therapy | Development region | Development stage |
|---|---|---|---|---|
| Telomelysin (OBP-301) (Suratadenoturev) | Esophageal cancer | Radiation therapy | Japan | Phase II (enrollment complete) |
| | | Chemoradiotherapy | U.S. | Phase I |
| | | Anti-PD-1 antibody pembrolizumab | Japan | Phase I (enrollment complete) |
| | Gastric/ gastroesophageal junction cancer | Anti-PD-1 antibody pembrolizumab | U.S. | Phase II (enrollment complete) |
| | Hepatocellular cancer (HCC) | Anti-PD-L1 antibody atezolizumab Molecular targeting drug | Japan | Phase I (complete) |
| | | Monotherapy | South Korea and Taiwan | Phase I (complete) |
| OBP-601 (Censavudine) | Progressive supranuclear palsy (PSP) | Monotherapy | U.S. | Phase IIa (enrollment complete) |
| | Amyotrophic lateral sclerosis (C9-ALS) / frontotemporal degeneration (FTD) | Monotherapy | U.S. | Phase IIa |
| OBP-2011 | Novel coronavirus infection (COVID-19) | TBD | Japan | Pre-clinical |
| OBP-702 | Solid tumor | Anti-PD-(L)1 antibody (expected) | U.S./Japan | Pre-clinical |
| TelomeScan (OBP-401) | Solid tumor | — | Japan | Clinical research |
| OBP-801 | Suppression of filtering bleb fibrosis after glaucoma surgery | Monotherapy | Japan | Pre-clinical |

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