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Non-consolidated Financial Results for the Three Months Ended March 31, 2025 [Japanese GAAP]

May 9, 2025

Company name: Oncolys BioPharma Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4588
URL: https://www.oncolys.com
Representative: Yasuo Urata, President & CEO
Contact: Kohei Hata, Executive Officer
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Scheduled date of commencing dividend payments: —
Availability of supplementary briefing material on financial results: No
Schedule of financial results briefing session: No

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

1. Financial Results for the Three Months Ended March 31, 2025 (January 1, 2025 to March 31, 2025)

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

	Net sales		Operating profit		Ordinary profit		Profit	
Three months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
March 31, 2025	–	–	(785)	–	(810)	–	(811)	–
March 31, 2024	–	(100.0)	(378)	–	(363)	–	(364)	–

	Basic earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
March 31, 2025	(32.66)	–
March 31, 2024	(18.24)	–

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of March 31, 2025	2,314	1,940	83.5
As of December 31, 2024	3,198	2,752	85.8

(Reference) Equity: As of March 31, 2025: ¥1,932 million
As of December 31, 2024: ¥2,744 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended December 31, 2024	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2025	–				
Fiscal year ending December 31, 2025 (Forecast)		0.00	–	0.00	0.00

(Note) Revision to the forecast for dividends announced most recently: No

3. Financial Results Forecast for the Fiscal Year Ending December 31, 2025 (January 1, 2025 to December 31, 2025)

Financial results forecast is not disclosed due to the difficulty of making reasonable estimates. For details, please see "1. Qualitative Information on Quarterly Financial Results for the Period under Review (3) Explanation of Financial Results Forecast and Other Forward-looking Information" on page 2 of the supplementary material.

*** Notes:**

(1) Accounting policies adopted specially for the preparation of quarterly financial statements: No

(2) Changes in accounting policies, changes in accounting estimates and retrospective restatement
1) Changes in accounting policies due to the revision of accounting standards: No
2) Changes in accounting policies other than 1) above: No
3) Changes in accounting estimates: No
4) Retrospective restatement: No

(3) Total number of issued shares (common shares)
1) Total number of issued shares at the end of the period (including treasury shares):
March 31, 2025: 24,961,600 shares
December 31, 2024: 24,961,600 shares

2) Total number of treasury shares at the end of the period:
March 31, 2025: 111,238 shares
December 31, 2024: 101,238 shares

3) Average number of shares during the period:
Three months ended March 31, 2025: 24,850,917 shares
Three months ended March 31, 2024: 19,971,483 shares

* Review of the attached quarterly financial statements by certified public accountants or an audit corporation: No

* 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, etc., please see "1. Qualitative Information on Quarterly Financial Results for the Period under Review (3) Explanation of Financial Results Forecast and Other Forward-looking Information" on page 2 of the supplementary material.

Table of Contents

1. Qualitative Information on Quarterly Financial Results for the Period under Review

(1) Explanation of Business Results

During the three months ended March 31, 2025, the Japanese economy began to show concerns over the tariff policy put forward by the U.S. Trump administration, with the index which indicates economic sentiment of large manufacturers in the Bank of Japan's Tankan survey for April 2025 worsening for the first time in four periods, among others. Furthermore, as for the overseas economy, with the additional imposition of tariffs by the U.S. increasing against a backdrop of shifts in the division of roles in international security, along with geopolitical risks such as Israel's conflict and Ukraine's situation, the unstable situation is expected to persist.

Under these circumstances, the Company has been pursuing a vision of "Providing new options to future cancer treatments, and leaving our footprint in the history of cancer treatment through those achievements." In particular, the Company is promoting research, development, and business activities with a focus on oncolytic virus OBP-301. The Company obtained approval for the manufacture and sale of regenerative medical products in April 2025. The Company moves from the conventional single business model dependent on licenses to a "hybrid business model" that combines a pharmaceutical company-type business model and a license-type business model with the development of the domestic business of OBP-301 as a pharmaceutical company-type business model. In addition, concerning LINE-1 inhibitor OBP-601 (censavudine), Transposon Therapeutics, Inc. (hereinafter "Transposon") is conducting clinical trials at its own expense based on a license agreement and proceeding with business activities.

For details of the Company's activities, please refer to "3. Supplemental Information (1) Research and development activities."

For the three months ended March 31, 2025, the Company recorded no business income (no business income in the same period of the previous fiscal year), and operating loss was ¥785,202 thousand (operating loss of ¥378,872 thousand in the same period of the previous fiscal year). In addition, the Company recorded interest income of ¥1,348 thousand as non-operating income, and interest expenses of ¥1,085 thousand, foreign exchange losses of ¥21,830 thousand, and amortization of restricted stock remuneration of ¥4,034 thousand as non-operating expenses, resulting in ordinary loss of ¥810,789 thousand (ordinary loss of ¥363,292 thousand in the same period of the previous fiscal year). As a result, loss was ¥811,653 thousand (net loss of ¥364,233 thousand in the same period of the previous fiscal year).

(2) Explanation of Financial Position

Assets at the end of the first quarter of the fiscal year under review were ¥2,314,439 thousand (27.6% decrease compared with the end of the previous fiscal year), owing partly to a decrease in cash and deposits. Liabilities were ¥373,883 thousand (16.3% decrease compared with the end of the previous fiscal year), owing partly to a decrease in loans payable. Net assets were ¥1,940,555 thousand (29.5% decrease compared with the end of the previous fiscal year), owing to decreases in retained earnings.

(3) Explanation of Financial Results Forecast and Other Forward-looking Information

The Company still has a small stable revenue base, and our financial results fluctuate greatly depending on the presence or absence of milestone revenue payments generated from our domestic distribution partnership agreement for OBP-301, achieving the development event of LINE-1 inhibitor OBP-601 by Transposon, and that company's IPO, M&A and other corporate action that generates milestone revenue payments.

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 forecast for the second quarter (cumulative).

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousand yen)

	As of December 31, 2024	As of March 31, 2025
Assets		
Current assets		
Cash and deposits	2,411,001	1,709,976
Supplies	4,578	4,251
Advance payments – other	480,969	230,505
Prepaid expenses	53,448	47,750
Accounts receivable – other	102,417	170,040
Consumption taxes receivable	45,829	56,026
Short-term loans receivable from subsidiaries and associates	–	29,906
Total current assets	3,098,244	2,248,457
Non-current assets		
Property, plant and equipment		
Buildings	3,128	392
Accumulated depreciation	(3,128)	(10)
Buildings, net	–	381
Machinery and equipment	924	–
Accumulated depreciation	(924)	–
Machinery and equipment, net	–	–
Tools, furniture and fixtures	67,782	–
Accumulated depreciation	(67,782)	–
Tools, furniture and fixtures, net	–	–
Total property, plant and equipment	–	381
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	47,445	14,953
Lease and guarantee deposits	22,174	26,100
Long-term prepaid expenses	9,955	3,507
Other	4	4
Total investments and other assets	100,614	65,600
Total non-current assets	100,614	65,981
Total assets	3,198,858	2,314,439

(Thousand yen)

	As of December 31, 2024	As of March 31, 2025
Liabilities		
Current liabilities		
Short-term loans payable	127,776	116,672
Lease obligations	10,177	10,210
Accounts payable – other	52,287	45,887
Accrued expenses	20,451	17,159
Income taxes payable	31,885	4,347
Deposits received	9,812	9,751
Total current liabilities	252,390	204,028
Non-current liabilities		
Long-term loans payable	166,656	144,432
Lease obligations	20,031	17,466
Provision for retirement benefits	7,570	7,955
Total non-current liabilities	194,258	169,854
Total liabilities	446,649	373,883
Net assets		
Shareholders' equity		
Capital stock	5,108,160	5,108,160
Capital surplus		
Legal capital surplus	2,694,489	2,694,489
Total capital surpluses	2,694,489	2,694,489
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(5,057,978)	(5,869,631)
Total retained earnings	(5,057,978)	(5,869,631)
Treasury shares	(142)	(142)
Total shareholders' equity	2,744,529	1,932,875
Share acquisition rights	7,680	7,680
Total net assets	2,752,209	1,940,555
Total liabilities and net assets	3,198,858	2,314,439

(2) Quarterly Statements of Income

Three Months Ended March 31

(Thousand yen)

	For the three months ended March 31, 2024	For the three months ended March 31, 2025
Net sales	–	–
Cost of sales	–	–
Gross profit	–	–
Selling, general and administrative expenses	378,872	785,202
Operating loss	(378,872)	(785,202)
Non-operating income		
Interest income	518	1,348
Foreign exchange gains	18,668	–
Other	–	14
Total non-operating income	19,187	1,362
Non-operating expenses		
Interest expenses	1,140	1,085
Share issuance costs	2,466	–
Amortization of restricted stock remuneration	–	4,034
Foreign exchange losses	–	21,830
Total non-operating expenses	3,607	26,949
Ordinary loss	(363,292)	(810,789)
Loss before income taxes	(363,292)	(810,789)
Income taxes - current	940	863
Total income taxes	940	863
Loss	(364,233)	(811,653)

(3) Notes to Quarterly Financial Statements

(Notes on going concern assumption)

There is no relevant information.

(Notes to statements of cash flows)

Quarterly statements of cash flows for the three months ended March 31, 2025 are not prepared. Depreciation for the three months ended March 31 is as follows:

(Thousand yen)

	For the three months ended March 31, 2024	For the three months ended March 31, 2025
Depreciation	—	10

(Notes in the case of significant changes in shareholders' equity)

There is no relevant information.

(Segment information, etc.)

[Segment information]

I. For the three months ended March 31, 2024

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

II. For the three months ended March 31, 2025

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

(Revenue recognition)

Disaggregation of revenue from contracts with customers

(Thousand yen)

	For the three months ended March 31, 2024	For the three months ended March 31, 2025
Goods / Services transferred at a point in time	—	—
Goods / Services transferred over time	—	—
Revenue from contracts with customers	—	—
Revenue from other sources	—	—
Net sales to outside customers	—	—

(Per share information)

Loss per share and the basis for its calculation are as follows.

Item	For the three months ended March 31, 2024	For the three months ended March 31, 2025
Loss per share	¥(18.24)	¥(32.66)
(Basis for the calculation)		
Loss (Thousand yen)	(364,233)	(811,653)
Amount not attributable to common shareholders (Thousand yen)	—	—
Loss relating to common shares (Thousand yen)	(364,233)	(811,653)
Average number of shares during the period (shares)	19,971,483	24,850,917
Outline of the residual shares with significant changes from the end of the previous fiscal year among the residual shares that were not included in the calculation of diluted earnings per share because they have no dilutive effects	—	—

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

(Significant subsequent events)

There is no relevant information.

3. Supplemental Information

(1) Research and Development Activities

Research and development expenses of the Company in the three months ended March 31, 2025 totaled ¥628,445 thousand for the drug discovery business. The status of research and development activities during the three months ended March 31, 2025 is as follows.

(1) Research and development structure

As of March 31, 2025, 22 persons belonged to the research and development department, accounting for 53.6% of the total number of employees.

(2) Research and development and business activities

The Company moves from the conventional single business model dependent on licenses to a "hybrid business model" that combines a pharmaceutical company-type business model and a license-type business model with the development of the domestic business of OBP-301 as a pharmaceutical company-type business model. The Company promoted research and development, and business activities under this policy.

1) Activities related to oncolytic virus OBP-301

Having been granted "SAKIGAKE designation" for regenerative medicine products for OBP-301 by the Ministry of Health, Labour and Welfare, the Company completed a "Phase II clinical trial in combination with radiation therapy for esophageal cancer (OBP101JP trial)." The results of this clinical trial were presented in October 2024 at the 62nd Annual Meeting of the Japan Society of Clinical Oncology held in Fukuoka. We began the SAKIGAKE comprehensive evaluation consultation for the application for approval of OBP-301 with the Pharmaceuticals and Medical Devices Agency (hereinafter "PMDA") in March 2025. After undergoing an examination of the contents, including the post-marketing clinical trial plan, we plan to submit an application for approval in the fiscal year ending December 31, 2025.

Regarding our domestic business, in February 2024, we signed an agreement with FUJIFILM Toyama Chemical to collaborate in OBP-301 sales and established a supply chain for OBP-301 from Henogen SA, the manufacturer, to medical institutions. We are now promoting various consultations regarding a sales system after products are launched in the market. In addition, we obtained approval for the manufacture and sale of regenerative medical products in April 2025. Furthermore, the administration of oncolytic adenovirus through an endoscope received patents in Japan in March 2025. The patents are not limited to OBP-301, but also covering OBP-702 and oncolytic adenovirus of other companies. The duration of patents is until May 2040.

Meanwhile, in the U.S., in December 2023, the Company signed an investigator-initiated clinical trial agreement with Cornell University, which in turn signed an investigator-initiated clinical trial agreement with MSD, to establish a joint development system for OBP-301 and the pembrolizumab. As a result, the Company and MSD are to equally share research and development expenses for a Phase II investigator-initiated clinical trial for the treatment of gastric cancer in patients who are receiving second-line treatment. In addition, the Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer, which was conducted by NRG Oncology, an authoritative cancer research organization in the U.S., was presented at the ASCO-GI (American Society of Clinical Oncology Gastrointestinal Cancers Symposium) held in January 2025, and it was announced that all 13 evaluable subjects had confirmed tumor disappearance at the site of administration.

Regarding overseas business development, in December 2024, we concluded a license agreement with Medigen of Taiwan for sales rights in Taiwan. After Medigen brings OBP-301 to market in Taiwan, the Company will supply the final product to Medigen at cost and will also receive royalty revenue from Medigen based on the sales proceeds.

Currently, OBP-301 has undergone the following three clinical trials in Japan and overseas, including the clinical trial for which submitting an application for approval has been in preparation or enrollment has been completed:

i) Phase II clinical trial in combination with radiation therapy for esophageal cancer (OBP101JP trial)
ii) Phase II investigator-initiated clinical trial of second-line treatment in combination with an anti-PD-1 antibody for gastric cancer/gastroesophageal junction cancer
iii) Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer

i) **Phase II clinical trial in combination with radiation therapy for esophageal cancer (OBP101JP trial)**

This clinical trial was conducted based on the "SAKIGAKE designation" of April 2019 at 17 clinical trial sites

around Japan and a notification of completion of clinical trial was submitted to the PMDA in September 2024. The results of the clinical trial were evaluated as detailed below, in consultations with medical experts and biological statisticians. Based on these results, the Company has been negotiating with the PMDA in order to file an application for manufacturing and marketing approval of OBP-301 in Japan. We began the SAKIGAKE comprehensive evaluation consultation in March 2025 with PMDA recognizing not only the results of the clinical trials until now but also the post-marketing clinical trial implementation plan as requirements for approval. After undergoing an examination, including the post-marketing clinical trial plan, we plan to submit an application for approval in the fiscal year ending December 31, 2025.

Furthermore, the results of OBP101JP trial of OBP-301 were presented at the 62nd Annual Meeting of Japan Society of Clinical Oncology held in Fukuoka in October 2024.

i-a) **Research and development activities**

Efficacy

The primary endpoint of "local complete response rate" (L-CR rate) was 41.7% (round off to the first decimal place; the same shall apply hereinafter), as evaluated by the Endoscope Central Judgment Committee. It was confirmed that the result was higher than the efficacy threshold of 30.2%, which was indicated in the protocol beforehand. In addition, the secondary endpoint of "local remarkable response rate" (L-RR rate; the cases in which the primary lesion did not completely disappear but shrink remarkably) was 16.7% and "local response rate" including L-RR ([L-CR + L-RR] rate) was 58.3%.

Furthermore, the one-year survival rate at the time of data cut-off in this study was 71.4%, which exceeded the one-year survival rate in the radiotherapy alone of 57.4% in "The Japan Esophageal Society national registered data."

At the time of 18 months, which is the longest follow-up period of this study, the local response rate was 63.9% and the local complete response rate was 50.0%. In addition, although the total survival rate at the time of 18 months was 53%, the cancer survival rate was 70% and the cancer survival rate of patients with local response was 90%. Moreover, improvement was recognized in 71% of patients with symptoms of dysphagia, which is included in the assessment indicators of QoL (Quality of Life) for esophageal cancer patients. These results suggested a possible increase in patient survival rates from the effect of OBP-301 on esophageal cancer locations.

Safety

The main side-effects related to OBP-301 included fever of 51.4% and the reduction of lymphocyte count or lymphopenia of 48.6%, both of which were mild to moderate or temporary change.

i-b) **Business activities**

The significant supply chain for stable supply of OBP-301 is divided into the preceding process of "manufacture in Belgium and shipment to FUJIFILM Toyama Chemical" and the post-process of "from FUJIFILM Toyama Chemical to medical institutions." For OBP-301 sales, the Company needs to obtain approval for manufacture and sale of regenerative medical products, in addition to approval for a new drug, and obtained approval for the manufacture and sale of regenerative medical products in April 2025.

Manufacture in Belgium and shipment to FUJIFILM Toyama Chemical

In order to ensure a smooth supply of OBP-301 after obtaining approval for its use in Japan, Henogen SA started manufacturing active pharmaceutical ingredients (API) for commercial products in November 2024 and achieved sufficient yields. After testing the quality of the APIs, we will complete drug formulation in the fiscal year ending December 31, 2025 by filling the vials with new APIs that prevent the formation of aggregates. MITSUI-SOKO HOLDINGS Co., Ltd., to whom we have entrusted the logistics operations of packaging, storage and transportation, has established a system that conforms to GCTP (Good Gene, Cellular, and Tissue-based Products Manufacturing Practice), the standard for the manufacturing and quality control of regenerative medicine products. The products shipped by Henogen SA will be stored at MITSUI-SOKO in Japan after import. Furthermore, Eurofins Analytical Science Laboratories (Kyoto City), a party entrusted with the shipment tests for OBP-301 after import, is preparing for the shipment tests for OBP-301. OBP-301, which will have been determined to be ready for shipment, will be shipped to FUJIFILM Toyama Chemical, our distribution partner.

Supply chain from FUJIFILM Toyama Chemical to medical institutions

The Company concluded a sales collaboration agreement with FUJIFILM Toyama Chemical in February 2024 to efficiently deliver OBP-301, which will have been determined to be ready for final shipment, to medical facilities in Japan. After a determination for shipment, OBP-301 will be shipped from the Company to FUJIFILM Toyama Chemical and provided to medical facilities through medical products companies designated by

FUJIFILM Toyama Chemical. The Company has concluded an agreement concerning safety information with FUJIFILM Toyama Chemical in September 2024. The Company will continue to conduct various consultations such as establishing a supply chain for smooth supply of OBP-301 after products are launched in the market.

Manufacture and sale of regenerative medical products

The Company will be positioned as a manufacturer and distributor shipping OBP-301 to Japan. Accordingly, its manufacturing and marketing are subject to review by the Tokyo Metropolitan Government for conformity to "GQP (Good Quality Practice)," and "GVP (Good Vigilance Practice)" and other requirements, and the Company needs to obtain approval for manufacture and sale of regenerative medical products.

In April 2025, the Company obtained approval for the manufacture and sale of regenerative medical products. Looking forward, we will further strengthen a system that conforms with GQP and GVP.

ii) **Phase II investigator-initiated clinical trial of second-line treatment in combination with an anti-PD-1 antibody for gastric cancer/gastroesophageal junction cancer**

Regarding the above ii) "Phase II investigator-initiated clinical trial of second-line treatment in combination with an anti-PD-1 antibody for gastric cancer/gastroesophageal junction cancer," Cornell University in the U.S. proposed the implementation of a new clinical trial and the payment of clinical trial expenses to MSD, after obtaining the prior agreement of the Company. In December 2023, agreements were concluded between the Company and Cornell University and between Cornell University and MSD, which established a joint development system.

This clinical trial combines the use of OBP-301 and anti-PD-1 antibody pembrolizumab as second-line treatment for patients with gastric/gastroesophageal junction cancer that is resilient to first-line treatment including anti-PD-1/PD-Li antibodies. Currently, the expenses for the clinical trial are shared equally between the Company and MSD, and administration is underway. With MSD's pembrolizumab achieving worldwide sales of over $25 billion in 2023, anti-PD-1/PD-Li antibodies are having a significant impact on the business of major pharmaceutical companies. If this second-line treatment for gastric cancer combining OBP-301 becomes established, it may provide a greater opportunity for major pharmaceutical companies that sell anti-PD-1/PD-Li antibodies to prescribe anti-PD-1/PD-Li antibodies. The Company expects that the results of this clinical trial will contribute to licensing activities for OBP-301 overseas.

iii) **Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer**

Regarding the above iii) "Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer," NRG Oncology, an authoritative cancer research organization in the U.S., has been leading the trial, and administration began in December 2021 with the purpose of investigating the safety and efficacy of using OBP-301 in combination with chemoradiotherapy, registering 15 patients. It was announced at the ASCO-GI (American Society of Clinical Oncology Gastrointestinal Cancers Symposium) held in January 2025, that tumor disappearance at the site of administration had been confirmed by endoscopic findings and pathological biopsy in all 13 patients who were subjects of the evaluation of effectiveness. OBP-301 has been designated as an orphan drug for esophageal cancer in the U.S., and this clinical trial is being conducted on that basis. Therefore, the Company will be able to receive preferential treatment in the form of grants and tax credits for clinical research expenses. Furthermore, first-mover rights protection will be granted after the approval of OBP-301 in the U.S., during which market exclusivity is to be granted.

2) Activities related to OBP-601 (censavudine), a LINE-1 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 conducted Phase IIb clinical trials as a treatment drug for HIV infection. The results demonstrated the non-inferiority of OBP-601 to existing drugs. BMS also obtained numerous clinical safety data for long-term OBP-601 toxicity studies and oncogenicity studies, but due to BMS's change of strategy, resulting in withdrawal from the HIV field, the license agreement was terminated. Results of a study by Brown University of the U.S. then suggested that nucleic acid-based reverse transcriptase inhibitors (NRTIs) of HIV suppress the aberrant expression of a retrotransposons. Subsequent research confirmed that OBP-601, which has the same effect, has high brain translocability compared to other NRTIs and strongly suppresses the production of a retrotransposon by greatly inhibiting a reverse transcriptase called LINE-1.

In June 2020, we concluded a licensing agreement worth more than $300 million worldwide with Transposon which had been planning to apply OBP-601 to the treatment of intractable neurological diseases focusing on this mechanism. In November of the same year, Transposon achieved its first milestone.

Transposon completed two double-blind Phase II clinical trials that make use of placebos. One covers

progressive supranuclear palsy (PSP), while the other is on amyotrophic lateral sclerosis (ALS), with the abnormal expression of the enzyme C9 ORF, and frontotemporal degeneration (FTD). In addition, enrollment proceeded under a single-arm Phase IIa clinical trial in Europe for the treatment of Aicardi-Goutières Syndrome (AGS). Furthermore, Transposon is moving forward on preparations for a new clinical trial for Alzheimer's disease based on the biomarker result indicating that OBP-601 suppressed inflammatory nerve damage, among others.

These clinical trials on OBP-601 are proceeding entirely at Transposon's expense based on the license agreement. In addition, Transposon is carrying out business activities based on the license agreement and may grant sublicenses for OBP-601 to pharmaceutical companies and other third parties. In case sublicensing proves successful, Transposon will pass on a certain percentage of revenue it obtains from sublicensees to the Company.

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.

i) **Phase II clinical trial for PSP**

Administration to the first patient under the Phase II clinical trial for PSP began in November 2021, and enrollment of the target number of patients was concluded in August 2022. Transposon disclosed the main details of the trial as follows at the 18th Alzheimer's and Parkinson's Diseases Conference (AD/PD2024) in March 2024.

1) The clinical trials incorporated 42 PSP patients.
2) The trials were conducted as double-blind trials, comparing four administration groups receiving 100 mg, 200 mg, 400 mg, and placebo per day. Following 6 months of administration in these double-blind trials, the administration was switched to 400 mg of OBP-601 for all patients and follow-up was provided for an additional 6 months.
3) OBP-601 indicated that it can be administered to PSP patients with safety and that loss of consciousness (1 patient in the 100 mg group) was reported as a serious side effect.
4) Regarding the neurofilament light chains (hereinafter "NfL") that shows inflammation of neural tissues, OBP-601 continuously reduced its concentration in cerebrospinal fluid.
5) IL-6 in cerebrospinal fluid, also an inflammatory biomarker like NfL, indicated a similar change.
6) The Progressive Supranuclear Palsy Rating Scale (PSPRS) suggested that OBP-601 can slow the worsening of symptoms.
7) With these above results, the clinical trials suggested that OBP-601 suppresses damage to the cerebral nerves from inflammation and the progression of PSP disease by suppressing Line-1 in the brain.

Transposon is currently moving forward on specific preparations for Phase III clinical trials for PSP with the U.S. Food & Drug Administration (FDA), such as holding the End of Phase II meeting to aim for starting Phase III clinical trials for PSP in parallel with business activities, including licensing to third parties. The FDA designated OBP-601 for PSP for Fast Track, which is a review system designed to facilitate new-drug approval and review, in May 2024.

ii) **Phase II clinical trial for C9-ALS/FTD**

Administration under the clinical trial for C9-ALS/FTD began in January 2022. Target enrollment was concluded in March 2023, and the trial was completed. To date, there have been no reports of safety problems that necessitate the termination of the trials. Transposon presented the development status of OBP-601 for ALS at instances such as the 2024 Annual Northeast Amyotrophic Lateral Sclerosis Consortium (NEALS) Meeting in October 2024 and the Annual ALS Research Symposium in December 2024. The main final analysis results of the trial related to ALS after 48 weeks are as follows:

1) The OBP-601 administration group reduced primary biomarkers of neurodegeneration and neuroinflammation including NfL, neurofilament heavy chains (hereinafter "NfH"), and IL-6 in cerebrospinal fluid.
2) The scale for assessment of ALS function (ALSFRS-R) suggested effects of suppressing the progression of illness.
3) The OBP-601 administration group decreased the deterioration rate of Vital Capacity, which is an objective indicator of respiratory function that correlates with C9-ALS patient mortality, by approximately 50% compared with the placebo administration group.
4) The OBP-601 administration group indicated a decrease in significant values of NfL in a meta-analysis that comprehensively analyzed Phase II clinical trials for C9-ALS/FTD and PSP.

Transposon held the End of Phase II meeting regarding ALS with the FDA in January 2025. Transposon plans to move forward with Phase II / III clinical trials on OBP-601 for ALS.

iii) **Phase II clinical trial for Alzheimer's disease**

Transposon is currently moving forward on preparations for Phase II clinical trial in its attempt to administer OBP-601 for Alzheimer's disease due to the following reasons based on the results of Phase II clinical trials for PSP and ALS.

1) OBP-601 showed its effectiveness for PSP, which is a disease related to accumulation of Tau protein in the brain, as well as for ALS, which is a disease related to TAR DNA-binding protein of 43 kDa (TDP-43).
2) Since Alzheimer's disease is a disease related to Tau protein and TDP-43, Transposon believes that OBP-601 may also suppress inflammatory neurodegeneration and show its effectiveness.
   The Company supports the above view of Transposon.

iv) **Phase II clinical trial for AGS**

In July 2023, Transposon started administration under a Phase II clinical trial for AGS, a genetic disorder that causes microcephaly and severe mental retardation, in Europe. To date, there have been no reports of safety problems that necessitate the termination of the trials. However, Transposon has lowered the priority of AGS in order to prioritize pivotal study for PSP and ALS and starting Phase II clinical trial for Alzheimer's disease by reviewing the development strategy of OBP-601.

3) Activities related to next-generation oncolytic virus OBP-702

OBP-702 is a second-generation virotherapeutic drug with two anti-tumor effects, combining the “oncogene therapy” that uses a novel oncolytic virus that carries the powerful in vivo cancer suppressor gene p53 in the vector with the “oncolytic functions” of OBP-301. A research group led by Professor Toshiyoshi Fujiwara of the Department of Gastroenterological Surgery, Transplant, and Surgical Oncology of Okayama University is moving forward on preparations for investigator-initiated clinical trial for pancreatic cancer, which was adopted as a grant program by the Japan Agency for Medical Research and Development (AMED) in March 2025. An experiment on gemcitabine-resistant pancreatic cancer cell lines using mouse models, OBP-702, used in combination with PD-L1 antibodies, has already exhibited stronger anti-tumor effects alone. It has also been shown to have a lethal effect on cancer associated fibroblasts (CAF), which are problematic in cancer therapy. It is expected that OBP-702 will be developed as a new treatment method for pancreatic cancer and other refractory cancers that are considered to be difficult to treat due to CAF.

As with the sequence of the development of OBP-301 for esophageal cancer, the Company’s policy is to take over the clinical development after Okayama University considers the safety and usage in the clinical trials for OBP-702, and move forward on the development, while considering the distinction of its business from that of OBP-301.

4) Activities related to OBP-2011 for the treatment of viral infectious diseases

Based on experimental outcomes, the Company assumes that OBP-2011 inhibits nucleocapsids, although 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, and the concentration of management resources on OBP-301 to apply for approval. Going forward, the Company will proceed with clarifying the detailed mechanism of action for OBP-2011 by conducting collaborative research with Kagoshima University and will consider new indications for RNA viruses other than coronaviruses.

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

The Company is conducting image learning of live cancer cells within the blood that TelomeScan fluoresced for automatic judgment by AI, aimed at establishing a platform for automated detection. However, the development has been delayed due to more time required to acquire the large number of images for image learning than initially planned. We have lowered the priority of these activities in order to concentrate management resources on OBP-301 to submit for approval.

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 (DLT) 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 were presented at a meeting of the Japanese Ophthalmological Society in April 2023 and at an annual meeting of the Association for Research in Vision and Ophthalmology (ARVO). Furthermore, use invention of OBP-801 related to “suppression of filtering bleb fibrosis after glaucoma surgery” and “age-related macular degeneration” received patents in Japan in July 2024. We have lowered the priority of these activities in order to concentrate management resources on OBP-301 to submit for approval.

The development status of pipeline products is as follows.

Product	Indication	Combination therapy	Development region	Development stage
OBP-301 (suratadenoturev)	Esophageal cancer	Radiation therapy	Japan	Phase II complete (SAKIGAKE comprehensive evaluation consultation)
		Chemoradiotherapy	U.S.	Phase I
		Anti-PD-1 antibody pembrolizumab	Japan	Phase I (complete)
	Gastric / gastroesophageal junction cancer	Anti-PD-1 antibody pembrolizumab (third-line treatment)	U.S.	Phase II (complete)
		Anti-PD-1 antibody pembrolizumab (second-line treatment)	U.S.	Phase II
	Hepatocellular cancer (HCC)	Monotherapy	South Korea and Taiwan	Phase I (complete)
OBP-601 (censavudine)	Progressive supranuclear palsy (PSP)	Monotherapy (double-blind trial)	U.S.	Phase II (Phase III preparation)
	Amyotrophic lateral sclerosis (ALS)	Monotherapy (double-blind trial)	U.S. and Europe	Phase II (Phase II / III preparation)
	Alzheimer's disease	TBD	U.S.	Phase II preparation
	Aicardi-Goutières Syndrome (AGS)	Monotherapy	Europe	Phase II
OBP-702	Pancreatic cancer	TBD	Japan	Pre-clinical (Phase I preparation)
OBP-2011	Viral infectious diseases	TBD	Japan	Pre-clinical
TelomeScan (OBP-401)	Solid tumor	—	Japan	Clinical research
OBP-801	Suppression of filtering bleb fibrosis after glaucoma surgery	—	Japan	Pre-clinical