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Non-consolidated Financial Results for the Nine Months Ended September 30, 2025 [Japanese GAAP]

November 7, 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
Email: oncolys_information@oncolys.com
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 Nine Months Ended September 30, 2025 (January 1, 2025 to September 30, 2025)

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

	Net sales		Operating profit		Ordinary profit		Profit	
Nine months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
September 30, 2025	28	(9.0)	(1,571)	–	(1,614)	–	(1,617)	–
September 30, 2024	31	(50.2)	(1,230)	–	(1,243)	–	(1,246)	–

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2025	(64.63)	–
September 30, 2024	(59.56)	–

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of September 30, 2025	2,188	1,770	79.1
As of December 31, 2024	3,198	2,752	85.8

(Reference) Equity: As of September 30, 2025: ¥1,731 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	–	0.00	–		
Fiscal year ending December 31, 2025 (Forecast)				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):
September 30, 2025: 25,866,600 shares
December 31, 2024: 24,961,600 shares

2) Total number of treasury shares at the end of the period:
September 30, 2025: 17,641 shares
December 31, 2024: 101,238 shares

3) Average number of shares during the period:
Nine months ended September 30, 2025: 25,018,117 shares
Nine months ended September 30, 2024: 20,932,636 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.

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

(1) Explanation of Business Results

During the nine months ended September 30, 2025, although uncertainties increased due to U.S. tariff policy, the Japanese economy saw robust corporate activities, with the expectation of limited impacts of the tariff policy following the agreement between Japan and the U.S. Furthermore, the unstable situation for the overseas economy is expected to improve due to declining risk factors such as signs of a resolution of the Israel conflict.

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 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 nine months ended September 30, 2025, the Company recorded net sales of ¥28,546 thousand (net sales of ¥31,384 thousand in the same period of the previous fiscal year), and operating loss was ¥1,571,067 thousand (operating loss of ¥1,230,138 thousand in the same period of the previous fiscal year). In addition, the Company recorded interest income of ¥3,348 thousand, and other items as non-operating income, and interest expenses of ¥3,803 thousand, amortization of restricted stock remuneration of ¥6,098 thousand, share acquisition rights issuance costs of ¥7,177 thousand, share issuance costs of ¥1,513 thousand, foreign exchange losses of ¥28,296 thousand, and other items as non-operating expenses, resulting in ordinary loss of ¥1,614,576 thousand (ordinary loss of ¥1,243,866 thousand in the same period of the previous fiscal year). As a result, loss was ¥1,617,044 thousand (net loss of ¥1,246,692 thousand in the same period of the previous fiscal year).

(2) Explanation of Financial Position

Assets at the end of the third quarter of the fiscal year under review were ¥2,188,416 thousand (31.6% decrease compared with the end of the previous fiscal year), owing partly to a decrease in cash and deposits. Liabilities were ¥417,560 thousand (6.5% decrease compared with the end of the previous fiscal year), owing partly to a decrease in income taxes payable. Net assets were ¥1,770,855 thousand (35.7% decrease compared with the end of the previous fiscal year), owing partly to loss incurred.

(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.

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousand yen)

	As of December 31, 2024	As of September 30, 2025
Assets		
Current assets		
Cash and deposits	2,411,001	1,351,952
Accounts receivable – trade	–	29,762
Supplies	4,578	3,819
Advance payments – other	480,969	334,313
Prepaid expenses	53,448	75,121
Accounts receivable – other	102,417	239,101
Income taxes refund receivable	–	5,785
Consumption taxes receivable	45,829	27,479
Short-term loans receivable from subsidiaries and associates	–	44,643
Other	–	10
Total current assets	3,098,244	2,111,987
Non-current assets		
Property, plant and equipment		
Buildings	3,128	5,950
Accumulated depreciation	(3,128)	(3,233)
Buildings, net	–	2,717
Machinery and equipment	924	924
Accumulated depreciation	(924)	(924)
Machinery and equipment, net	–	–
Tools, furniture and fixtures	67,782	44,252
Accumulated depreciation	(67,782)	(44,091)
Tools, furniture and fixtures, net	–	160
Total property, plant and equipment	–	2,877
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	–
Lease and guarantee deposits	22,174	25,903
Long-term prepaid expenses	9,955	26,607
Other	4	4
Total investments and other assets	100,614	73,551
Total non-current assets	100,614	76,428
Total assets	3,198,858	2,188,416

(Thousand yen)

	As of December 31, 2024	As of September 30, 2025
Liabilities		
Current liabilities		
Short-term loans payable	127,776	238,888
Lease obligations	10,177	10,277
Accounts payable – other	52,287	39,891
Accrued expenses	20,451	18,705
Income taxes payable	31,885	–
Deposits received	9,812	11,128
Total current liabilities	252,390	318,891
Non-current liabilities		
Long-term loans payable	166,656	77,768
Lease obligations	20,031	12,311
Provision for retirement benefits	7,570	8,590
Total non-current liabilities	194,258	98,669
Total liabilities	446,649	417,560
Net assets		
Shareholders' equity		
Capital stock	5,108,160	3,015,317
Capital surplus		
Legal capital surplus	2,694,489	270,645
Other capital surplus	–	62,763
Total capital surpluses	2,694,489	333,409
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(5,057,978)	(1,617,044)
Total retained earnings	(5,057,978)	(1,617,044)
Treasury shares	(142)	(17)
Total shareholders' equity	2,744,529	1,731,665
Share acquisition rights	7,680	39,190
Total net assets	2,752,209	1,770,855
Total liabilities and net assets	3,198,858	2,188,416

(2) Quarterly Statements of Income

Nine Months Ended September 30

(Thousand yen)

	For the nine months ended September 30, 2024	For the nine months ended September 30, 2025
Net sales	31,384	28,546
Gross profit	31,384	28,546
Selling, general and administrative expenses	1,261,522	1,599,613
Operating loss	(1,230,138)	(1,571,067)
Non-operating income		
Interest income	1,623	3,348
Dividend income	5	3
Foreign exchange gains	4,293	–
Other	22	30
Total non-operating income	5,945	3,381
Non-operating expenses		
Interest expenses	3,454	3,803
Amortization of restricted stock remuneration	3,274	6,098
Foreign exchange losses	–	28,296
Share acquisition rights issuance costs	7,412	7,177
Share issuance costs	5,457	1,513
Other	73	–
Total non-operating expenses	19,673	46,890
Ordinary loss	(1,243,866)	(1,614,576)
Loss before income taxes	(1,243,866)	(1,614,576)
Income taxes – current	2,825	2,467
Total income taxes	2,825	2,467
Loss	(1,246,692)	(1,617,044)

(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 nine months ended September 30, 2025 are not prepared. Depreciation for the nine months ended September 30 is as follows:

(Thousand yen)

	For the nine months ended September 30, 2024	For the nine months ended September 30, 2025
Depreciation	380	136

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

Based on the resolution by the Annual General Meeting of Shareholders held on March 27, 2025, a capital reduction became effective on May 31, 2025, and the Company reduced capital stock by ¥2,363,488 thousand and legal capital surplus by ¥2,694,489 thousand and transferred them to other capital surplus. Thereafter, the Company reduced the entire amount of other capital surplus of ¥5,057,978 thousand and transferred it to retained earnings brought forward to compensate the deficit.

In addition, the Company disposed of treasury shares as restricted stock remuneration, based on the resolution by the Board of Directors at its meeting held on June 13, 2025. Due to this disposal of treasury shares, other capital surplus increased by ¥62,763 thousand and treasury shares decreased by ¥126 thousand.

Furthermore, the 21st series share acquisition rights were issued as of August 4, 2025. Due to the payment made upon the exercise of the rights, capital stock and legal capital surplus each increased by ¥270,645 thousand.

As a result of the above, during the nine months ended September 30, 2025, capital stock decreased by ¥2,092,842 thousand and capital surplus by ¥2,361,079 thousand. At the end of the period, capital stock was ¥3,015,317 thousand and capital surplus was ¥333,409 thousand.

(Segment information, etc.)

[Segment information]

I. For the nine months ended September 30, 2024

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

II. For the nine months ended September 30, 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 nine months ended September 30, 2024	For the nine months ended September 30, 2025
Goods / Services transferred at a point in time	31,384	28,546
Goods / Services transferred over time	—	—
Revenue from contracts with customers	31,384	28,546
Revenue from other sources	—	—
Net sales to outside customers	31,384	28,546

(Per share information)

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

Item	For the nine months ended September 30, 2024	For the nine months ended September 30, 2025
Loss per share	¥(59.56)	¥(64.63)
(Basis for the calculation)		
Loss (Thousand yen)	(1,246,692)	(1,617,044)
Amount not attributable to common shareholders (Thousand yen)	—	—
Loss relating to common shares (Thousand yen)	(1,246,692)	(1,617,044)
Average number of shares during the period (shares)	20,932,636	25,018,117
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	—	—

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

(Significant subsequent events)

Capital increase through exercise of share acquisition rights

During the period starting on October 1, 2025 and ending on October 31, 2025, a portion of the 21st series Share Acquisition Rights was exercised as follows:

(1) Class and number of shares issued	1,089,300 shares of common stock
(2) Number of units of share acquisition rights exercised	10,893 units
(3) Total amount exercised	696,204 thousand yen
(4) Amount of increase in capital stock	353,113 thousand yen
(5) Amount of increase in legal capital surplus	353,113 thousand yen

(Notes) 1. (4) Amount of increase in capital stock and (5) Amount of increase in legal capital surplus include transfer of share acquisition rights of 5,010 thousand yen each.

2. As a result of the above issuance of new shares upon exercise of stock acquisition rights, the total number of shares issued and outstanding as of October 31, 2025 was 26,955,900 shares, capital stock was 3,368,430 thousand yen, and legal capital surplus was 623,759 thousand yen.

3. Supplemental Information

(1) Research and Development Activities

Research and development expenses of the Company in the nine months ended September 30, 2025 totaled ¥1,184,237 thousand for the drug discovery business. The status of research and development activities during the nine months ended September 30, 2025 is as follows.

(1) Research and development structure

As of September 30, 2025, 25 persons belonged to the research and development department, accounting for 59.5% of the total number of employees.

(2) Research and development and business activities

The Company has moved 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

The Company completed a "Phase II clinical trial in combination with radiation therapy for esophageal cancer (OBP101JP trial)" for OBP-301 in Japan. We have been proceeding with the SAKIGAKE comprehensive evaluation consultation for the application for approval of OBP-301 with the Pharmaceuticals and Medical Devices Agency (hereinafter "PMDA"). We expect to subsequently receive confirmation documents for application for the categories of clinical trials, non-clinical trials, quality, GCTP, and assurance, by each category. As scheduled, we will submit such applications for approval of OBP-301 as regenerative medicine products for esophageal cancer in the fourth quarter of the fiscal year ending December 31, 2025. Meanwhile, in September 2025, we submitted an application for the designation of OBP-301 as a regenerative medicine product for rare diseases (hereinafter an "orphan drug"). We assume that OBP-301 will be designated as an orphan drug in the fourth quarter of the fiscal year ending December 31, 2025.

Regarding our domestic business, in February 2024, we signed an agreement with FUJIFILM Toyama Chemical Co., Ltd. (hereinafter "FUJIFILM Toyama Chemical") to collaborate in OBP-301 sales and are establishing a supply chain for OBP-301 from Henogen SA, the manufacturer, through MITSUI-SOKO HOLDINGS Co., Ltd. (hereinafter "MITSUI-SOKO HOLDINGS"), responsible for storage and other operations for OBP-301 in Japan, to medical institutions. In September 2025, we concluded a quality agreement with MITSUI-SOKO HOLDINGS. In October 2025, Henogen SA commenced drug formulation and manufacturing in accordance with Good Manufacturing Practice (GMP) to obtain approval for new drugs. In addition, we obtained approval for the manufacture and sale of regenerative medical products in April 2025. Furthermore, patents were granted for the administration of oncolytic adenovirus through an endoscope in Japan in April 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. Based on the agreements, the Company and MSD are equally sharing 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, and conducting this clinical trial.

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) in January 2025, and it was announced that all 13 evaluable subjects had confirmed tumor disappearance at the site of administration. The result on the one-year survival rate in this investigator-initiated clinical trial is expected to be confirmed in the fiscal year ending December 31, 2025.

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.

OBP-301 is undergoing 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)
i-a) Research and development activities

This clinical trial was conducted based on the "SAKIGAKE designation" of April 2019 at 17 clinical trial sites around Japan and the results were presented at the 62nd Annual Meeting of Japan Society of Clinical Oncology held in Fukuoka in October 2024 as detailed below.

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.

At the ESMO-GI 2025 (European Society for Medical Oncology Gastrointestinal Cancers Congress) held in Spain in July 2025, it was reported as the study of Dr. Ken Kato of National Cancer Center Hospital, et al. that the L-CR rate was 22% for patients with stage II or III esophageal cancer who received the radiotherapy alone at 12 facilities in Japan from 2014 to 2023.

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 "sale from FUJIFILM Toyama Chemical to medical institutions." The Company is striving to establish a supply chain with these partners. The Company obtained approval for the manufacture and sale of regenerative medical products required for OBP-301 sales 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, in October 2025, Henogen SA started drug formulation by filling the vials with new active pharmaceutical ingredients (APIs) that prevent the formation of aggregates. In August 2025, it was confirmed that stability of formulations are maintained for the twelve-month period after drug formulation with new APIs. We plan to confirm its stability data for the eighteen-month period in the first half of the fiscal year ending December 31, 2026.

MITSUI-SOKO HOLDINGS 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 HOLDINGS 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 will continue to work on activities 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 is positioned as a manufacturer and distributor shipping OBP-301 to Japan. 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 (Good Quality Practice)," and "GVP (Good Vigilance Practice)."

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-L1 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-L1 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-L1 antibodies to prescribe anti-PD-1/PD-L1 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. The result on the one-year survival rate in this investigator-initiated clinical trial is expected to be confirmed in the fiscal year ending December 31, 2025.

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.

The Company is moving forward on preparations to initiate clinical trials on OBP-301 in new fields, in addition to the above three clinical trials.

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). It is moving forward on preparations for the next-phase clinical trials. It is also proceeding with preparations for a new clinical trial for Alzheimer's disease based on the biomarker result, among others, indicating that OBP-601 suppressed inflammatory nerve damage. It has lowered the priority of a single-arm Phase II clinical trial in Europe for the treatment of Aicardi-Goutières Syndrome (AGS).

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.

i) Phase III 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 / III clinical trial for ALS

Administration under the Phase II 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. Furthermore, OBP-601 was selected for inclusion in the HEALEY ALS Platform Trial with the recognition of the above results of the clinical trial. Transposon plans to begin Phase II / III clinical trials for ALS by utilizing the HEALEY ALS Platform Trial in 2025.

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 Alzheimer's Drug Discovery Foundation (hereinafter the "ADDF") has determined that OBP-601 is promising for the treatment of Alzheimer's disease with its recognition of the above results of the clinical trial and decided that Transposon will receive an investment of approximately $5 million from the ADDF. Transposon plans to begin a Phase II clinical trial for Alzheimer's disease by utilizing the funds from the ADDF in the fourth quarter of 2025.

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 obtaining approvals 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, regarding the use patent for OBP-801 in the ophthalmic field that we received in Japan in 2024, the extension of the scope of patent protection was granted in October 2025. 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 (Enrollment complete)
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