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



August 8, 2025

Company name: Oncolys BioPharma Inc.
 Stock exchange listing: Tokyo Stock Exchange
 Code number: 4588
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 Scheduled date of filing semi-annual securities report: August 8, 2025
 Scheduled date of commencing dividend payments: —
 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 Six Months Ended June 30, 2025 (January 1, 2025 to June 30, 2025)

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

	Net sales		Operating profit		Ordinary profit		Profit	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Six months ended								
June 30, 2025	28	(9.0)	(1,267)	—	(1,311)	—	(1,313)	—
June 30, 2024	31	(50.2)	(793)	—	(752)	—	(754)	—

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
Six months ended		
June 30, 2025	(52.85)	—
June 30, 2024	(36.96)	—

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of June 30, 2025	1,932	1,438	74.1
As of December 31, 2024	3,198	2,752	85.8

(Reference) Equity: As of June 30, 2025: ¥1,431 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 semi-annual 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):

June 30, 2025: 24,961,600 shares

December 31, 2024: 24,961,600 shares

2) Total number of treasury shares at the end of the period:

June 30, 2025: 114,238 shares

December 31, 2024: 101,238 shares

3) Average number of shares during the period:

Six months ended June 30, 2025: 24,849,129 shares

Six months ended June 30, 2024: 20,421,423 shares

* These semi-annual financial results are outside the scope of review by certified public accountants or an audit corporation.

* 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 six months ended June 30, 2025, the Japanese economy faced heightened uncertainties over the future, among others, with deteriorated economic sentiment of export related industries including motor vehicles, which are exposed to the impacts of tariff policy of the U.S. Trump administration, as indicated in the Bank of Japan's Tankan survey for July 2025. Furthermore, the unstable situation for the overseas economy is expected to persist due to political factors such as the policy trend in the U.S., as well as the continued uncertainties over the Middle East.

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 OBP-301 virotherapy for cancer. 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 six months ended June 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 ¥1,267,127 thousand (operating loss of ¥793,371 thousand in the same period of the previous fiscal year). In addition, the Company recorded interest income of ¥1,824 thousand as non-operating income, and interest expenses of ¥2,289 thousand, amortization of restricted stock remuneration of ¥5,030 thousand, foreign exchange losses of ¥39,061 thousand, and other items as non-operating expenses, resulting in ordinary loss of ¥1,311,654 thousand (ordinary loss of ¥752,997 thousand in the same period of the previous fiscal year). As a result, loss was ¥1,313,230 thousand (net loss of ¥754,868 thousand in the same period of the previous fiscal year).

(2) Explanation of Financial Position

Assets at the end of the semi-annual period of the fiscal year under review were ¥1,932,328 thousand (39.6% decrease compared with the end of the previous fiscal year), owing partly to a decrease in cash and deposits. Liabilities were ¥493,349 thousand (10.5% increase compared with the end of the previous fiscal year), owing partly to an increase in accounts payable – other. Net assets were ¥1,438,978 thousand (47.7% 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. Semi-annual Financial Statements and Primary Notes

(1) Semi-annual Balance Sheets

(Thousand yen)

	As of December 31, 2024	As of June 30, 2025
Assets		
Current assets		
Cash and deposits	2,411,001	1,387,607
Accounts receivable – trade	–	28,962
Supplies	4,578	4,659
Advance payments – other	480,969	154,781
Prepaid expenses	53,448	56,965
Accounts receivable – other	102,417	189,335
Consumption taxes receivable	45,829	18,371
Short-term loans receivable from subsidiaries and associates	–	28,962
Total current assets	3,098,244	1,869,644
Non-current assets		
Property, plant and equipment		
Buildings	3,128	4,050
Accumulated depreciation	(3,128)	(3,180)
Buildings, net	–	869
Machinery and equipment	924	924
Accumulated depreciation	(924)	(924)
Machinery and equipment, net	–	–
Tools, furniture and fixtures	67,782	67,975
Accumulated depreciation	(67,782)	(67,782)
Tools, furniture and fixtures, net	–	192
Total property, plant and equipment	–	1,062
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	14,481
Lease and guarantee deposits	22,174	26,100
Long-term prepaid expenses	9,955	–
Other	4	4
Total investments and other assets	100,614	61,621
Total non-current assets	100,614	62,683
Total assets	3,198,858	1,932,328

(Thousand yen)

	As of December 31, 2024	As of June 30, 2025
Liabilities		
Current liabilities		
Short-term loans payable	127,776	147,222
Lease obligations	10,177	10,243
Accounts payable – other	52,287	80,521
Accrued expenses	20,451	19,068
Income taxes payable	31,885	8,695
Deposits received	9,812	9,899
Total current liabilities	252,390	275,650
Non-current liabilities		
Long-term loans payable	166,656	194,436
Lease obligations	20,031	14,893
Provision for retirement benefits	7,570	8,369
Total non-current liabilities	194,258	217,698
Total liabilities	446,649	493,349
Net assets		
Shareholders' equity		
Capital stock	5,108,160	2,744,671
Capital surplus		
Legal capital surplus	2,694,489	–
Total capital surpluses	2,694,489	–
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(5,057,978)	(1,313,230)
Total retained earnings	(5,057,978)	(1,313,230)
Treasury shares	(142)	(142)
Total shareholders' equity	2,744,529	1,431,298
Share acquisition rights	7,680	7,680
Total net assets	2,752,209	1,438,978
Total liabilities and net assets	3,198,858	1,932,328

(2) Semi-annual Statements of Income

(Thousand yen)

	For the six months ended June 30, 2024	For the six months ended June 30, 2025
Net sales	31,384	28,546
Cost of sales	–	–
Gross profit	31,384	28,546
Selling, general and administrative expenses	824,755	1,295,673
Operating loss	(793,371)	(1,267,127)
Non-operating income		
Interest income	1,047	1,824
Dividend income	5	3
Foreign exchange gains	48,518	–
Other	22	27
Total non-operating income	49,593	1,854
Non-operating expenses		
Interest expenses	2,185	2,289
Amortization of restricted stock remuneration	2,183	5,030
Foreign exchange losses	–	39,061
Share acquisition rights issuance costs	2,310	–
Share issuance costs	2,466	–
Other	73	–
Total non-operating expenses	9,219	46,381
Ordinary loss	(752,997)	(1,311,654)
Loss before income taxes	(752,997)	(1,311,654)
Income taxes – current	1,871	1,576
Total income taxes	1,871	1,576
Loss	(754,868)	(1,313,230)

(3) Semi-annual Statements of Cash Flows

(Thousand yen)

	For the six months ended June 30, 2024	For the six months ended June 30, 2025
Cash flows from operating activities		
Loss before income taxes	(752,997)	(1,311,654)
Depreciation	–	52
Amortization of restricted stock remuneration	2,183	5,030
Share-based remuneration expenses	6,862	10,308
Increase (decrease) in provision for retirement benefits	(1,109)	798
Interest and dividend income	(1,052)	(1,827)
Interest expenses	2,185	2,289
Share acquisition rights issuance costs	2,310	–
Share issuance costs	2,466	–
Foreign exchange losses (gains)	(29,522)	27,344
Decrease (increase) in notes and accounts receivable – trade	(32,206)	(28,962)
Decrease (increase) in inventories	1,064	(81)
Decrease (increase) in prepaid expenses	(8,607)	(8,446)
Decrease (increase) in accounts receivable – other	(82,953)	(86,074)
Decrease (increase) in consumption taxes refund receivable	27,981	27,457
Decrease (increase) in advance payments – other	(107,125)	326,188
Increase (decrease) in accounts payable – other	(147,462)	28,233
Other, net	(1,406)	(22,201)
Subtotal	(1,119,389)	(1,031,542)
Interest and dividend income received	25	859
Interest expenses paid	(1,862)	(2,744)
Income taxes paid	(2,927)	(3,861)
Net cash provided by (used in) operating activities	(1,124,153)	(1,037,289)
Cash flows from investing activities		
Purchase of property, plant and equipment	–	(1,114)
Payments of leasehold and guarantee deposits	(1,424)	(3,925)
Proceeds from refund of lease and guarantee deposits	240	–
Net cash provided by (used in) investing activities	(1,184)	(5,040)
Cash flows from financing activities		
Proceeds from long-term loans payable	100,000	100,000
Repayments of long-term loans payable	(44,440)	(52,774)
Repayments of lease obligations	(4,929)	(5,072)
Proceeds from issuance of common shares	638,294	–
Payments for issuance of shares	(2,466)	–
Net cash provided by (used in) financing activities	686,458	42,153
Effect of exchange rate change on cash and cash equivalents	23,573	(23,217)
Net increase (decrease) in cash and cash equivalents	(415,305)	(1,023,393)
Cash and cash equivalents at beginning of period	1,287,763	2,165,918
Cash and cash equivalents at end of period	872,457	1,142,525

(4) Notes to Semi-annual Financial Statements

(Notes on going concern assumption)

There is no relevant information.

(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. As a result, at the end of the period, capital stock was ¥2,744,671 thousand and legal capital surplus was ¥0.

(Segment information, etc.)

[Segment information]

I. For the six months ended June 30, 2024

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

II. For the six months ended June 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 six months ended June 30, 2024	For the six months ended June 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

(Significant subsequent events)

1. Disposal of treasury shares as restricted stock remuneration

At a meeting of the Board of Directors held on June 13, 2025, the Company resolved that it shall pay monetary compensation claims totaled 63,447,500 yen as restricted stock remuneration to two Directors (excluding Outside Directors) and 35 Executive Officers and employees of the Company (hereinafter collectively the "Allottees"), and that upon the Allottees making in-kind contributions of the all monetary compensation claims, 102,500 shares of the Company's common stock shall be allotted as specified transfer-restricted shares. The payment procedures were completed on July 2, 2025 as described below, with the right of one allottee forfeited by the due date of payment.

Outline of disposal

(1) Due date of payment	July 2, 2025
(2) Class and number of shares subject to disposal	101,600 shares of the Company's common stock
(3) Disposal price	619 yen per share
(4) Total value of shares disposed	62,890,400 yen
(5) Disposal recipients, number thereof, and number of shares disposed of	27,000 shares for 2 Directors of the Company 74,600 shares for 34 Executive Officers and employees of the Company

Purpose and reason for disposal

The Company has introduced a restricted stock compensation plan (hereinafter the “Plan”), under which restricted shares are granted, in order for Directors (excluding Outside Directors), Executive Officers, and employees of the Company to further enhance their motivation to contribute to an increase in the stock price and corporate value through their sharing the benefits and risks of stock price fluctuations with shareholders. The Company has set the transfer restriction period of over two years in order for the Allottees to aim for achieving the purpose of the introduction of the Plan, which is further enhancing their motivation to contribute to an increase in the stock price and corporate value through their sharing the benefits and disadvantages of stock price fluctuations with shareholders.

2. Issuance of the 21st series share acquisition rights (with exercise price adjustment clause) through third-party allotment

The Company resolved, at the Board of Directors meeting held on July 18, 2025, to issue share acquisition rights (with exercise price adjustment clause) (hereinafter the “Share Acquisition Rights”) through third-party allotment by designating SMBC Nikko Securities Inc. as a scheduled allottee (hereinafter “SMBC Nikko Securities” or the “Scheduled Allottee”), and confirmed the completion of the payment of the total issue price on August 4, 2025.

Outline of the 21st series share acquisition rights (with exercise price adjustment clause) through third-party allotment

Date of allotment	August 4, 2025
Number of share acquisition rights issued	43,300 units
Class and number of shares to be issued upon exercise of stock acquisition rights	100 shares of the Company’s common stock per share acquisition right
Issue price	920 yen per Share Acquisition Right (Total amount: 39,836,000 yen)
Number of potential shares resulting from the issuance	Number of potential shares: 4,330,000 shares There is no upper limit of the exercise price. While the lower limit of exercise price is 312 yen, the number of potential shares even at the lower limit of exercise price is 4,330,000.
Amount of funds to be procured	2,729,426,000 yen (estimated net proceeds) (Note)
Exercise price and conditions for adjustment of exercise price	Initial exercise price: 623 yen The exercise price is adjusted, on the effective date of each exercise request of the Share Acquisition Rights, to the amount equivalent to 91% of the closing price of the Company’s common stock in regular trading on the Tokyo Stock Exchange, Inc. on the trading day immediately preceding the said effective date. If the price after adjustment is lower than the lower limit of exercise price, the lower limit of exercise price will be the exercise price after the adjustment.
Capital stock and legal capital surplus to be increased where shares are issued upon the exercise of share acquisition rights	Where shares of common stock are issued upon the exercise of the Share Acquisition Rights, the amount of capital stock to be increased shall be one half of the maximum increase amount of capital stock, as calculated in accordance with the provisions of Article 17 of the Regulations on Corporate Accounting, with any fraction less than one yen resulting from the calculation being rounded up to the nearest one yen. The amount of legal capital surplus to be increased is the amount obtained by subtracting the said amount of capital stock to be increased from the maximum amount of increase of capital stock.
Method of offering or allotment	Third-party allotment
Allottee	SMBC Nikko Securities Inc.
Exercise period	From August 5, 2025 to August 4, 2026

	Specific use	Amount (Million yen)
	Use of funds	(i) Costs for manufacture, sale, and distribution of OBP-301 after starting its sale
(ii) Costs for expanding indications of OBP-301 other than the indication under its first approval		767
(iii) Costs for survey, etc. after manufacture and sale of OBP-301 after starting its sale		1,086
Total		2,729
Other	After a notification in accordance with the Financial Instruments and Exchange Act came into effect, the Company executed an agreement on purchase of the Share Acquisition Rights (hereinafter the “Agreement on Purchase of the Share Acquisition Right”) with SMBC Nikko Securities. The Agreement on Purchase of the Share Acquisition Rights stipulates that SMBC Nikko Securities shall not be entitled to transfer the Share Acquisition Rights to a third-party other than the Company, without prior consent of the Company.	

(Note) The amount of funds to be procured is the sum of the total amount to be paid in for the Share Acquisition Rights plus the total amount of property to be contributed upon exercise of the Share Acquisition Rights, less an estimated amount of issuance expenses related to the Share Acquisition Rights. The total amount of property to be contributed upon exercise of the Share Acquisition Rights is the amount assuming that all the Share Acquisition Rights are exercised with the initial exercise price. Therefore, if the exercise price of the Share Acquisition Rights is revised or adjusted, the amount of funds procured will increase or decrease. Furthermore, the amount of funds procured will decrease if the Share Acquisition Rights are not exercised within their exercisable period or if the Company cancels the Share Acquisition Rights it acquired.

3. Capital increase through exercise of share acquisition rights

During the period starting on August 5, 2025 and ending on August 6, 2025, a portion of the 21st series Share Acquisition Rights was exercised as follows:

(1) Class and number of shares issued	28,000 shares of common stock
(2) Number of units of share acquisition rights exercised	280 units
(3) Total amount exercised	15,086 thousand yen
(4) Amount of increase in capital stock	7,672 thousand yen
(5) Amount of increase in legal capital surplus	7,672 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 128 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 August 6, 2025 was 24,989,600 shares, capital stock was 2,752,343 thousand yen, and legal capital surplus was 7,672 thousand yen.

3. Supplemental Information

(1) Research and Development Activities

Research and development expenses of the Company in the six months ended June 30, 2025 totaled ¥1,017,169 thousand for the drug discovery business. The status of research and development activities during the six months ended June 30, 2025 is as follows.

(1) Research and development structure

As of June 30, 2025, 24 persons belonged to the research and development department, accounting for 58.54% 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”), and the consultation has been progressing smoothly. As we expect to receive confirmation documents for application for which PMDA deems that an application for approval of OBP-301 may be submitted for the categories of clinical trial, non-clinical trials, quality, GCTP, and assurance, by each category from the third quarter of the fiscal year ending September 30, 2025, we plan to 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.

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 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 second half of 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.

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.

With these above results, we began the SAKIGAKE comprehensive evaluation consultation with PMDA in March 2025. We plan to submit an application for approval in the fiscal year ending December 31, 2025.

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.

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, Henogen SA started manufacturing active pharmaceutical ingredients (API) for commercial products in November 2024 and achieved sufficient yields. We will complete drug formulation by filling the vials with new APIs that prevent the formation of aggregates in the fourth quarter of the fiscal year ending December 31, 2025. It has already been confirmed that stability of formulations are maintained for the nine-month period after drug formulation with new APIs that prevent the formation of aggregates

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 will be 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-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. The result on the one-year survival rate in this investigator-initiated clinical trial is expected to be confirmed in the second half of 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.

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 retrotransposon. 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 II 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 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. Transposon plans to move forward with Phase II / III clinical trials on OBP-601 for ALS. 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, 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 (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