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Non-consolidated Financial Results for the Six Months Ended June 30, 2026 [Japanese GAAP]

August 7, 2026

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 filing semi-annual securities report: August 7, 2026
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, 2026 (January 1, 2026 to June 30, 2026)

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

	Net sales		Operating profit		Ordinary profit		Profit	
Six months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
June 30, 2026	503	1,662.4	(767)	–	(760)	–	(762)	–
June 30, 2025	28	(9.0)	(1,267)	–	(1,311)	–	(1,313)	–

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
June 30, 2026	(26.03)	–
June 30, 2025	(52.85)	–

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of June 30, 2026	4,510	3,257	72.1
As of December 31, 2025	4,555	3,999	87.6

(Reference) Equity: As of June 30, 2026: ¥3,250 million
As of December 31, 2025: ¥3,992 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, 2025	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2026	–	0.00			
Fiscal year ending December 31, 2026 (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, 2026 (January 1, 2026 to December 31, 2026)

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, 2026: 29,319,700 shares
December 31, 2025: 29,291,600 shares

2) Total number of treasury shares at the end of the period:
June 30, 2026: 24,943 shares
December 31, 2025: 17,641 shares

3) Average number of shares during the period:
Six months ended June 30, 2026: 29,284,197 shares
Six months ended June 30, 2025: 24,849,129 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, 2026, the Japanese economy demonstrated its robustness, with demand related to artificial intelligence (AI) and semiconductors acting as a strong tailwind, despite surging prices of energy resources associated with the 2026 Iran war and higher import prices caused by the yen's depreciation. The global economy is also expected to continue to expand against the backdrop of easing geopolitical risks and strong stock markets, despite rising crude oil prices and higher prices caused by supply disruptions stemming from growing instability in the Middle East.

Under these circumstances, the Company is 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 has been promoting research, development, and business activities with a focus on cancer virotherapy OBP-301, and obtained its manufacturing and marketing approval as a regenerative medicine product for esophageal cancer in June 2026. Associated with the manufacturing and marketing approval, the Company received a milestone revenue payment and advances from FUJIFILM Toyama Chemical Co., Ltd. (hereinafter "FUJIFILM Toyama Chemical"), the marketing partner, in July 2026. A plenary meeting of the Central Social Insurance Medical Council was held in August 2026, and the drug price of OBP-301 was approved at ¥3,102,489 (¥9,307,467/patient). 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, 2026, the Company recorded net sales of ¥503,090 thousand (net sales of ¥28,546 thousand in the same period of the previous fiscal year), and operating loss was ¥767,606 thousand (operating loss of ¥1,267,127 thousand in the same period of the previous fiscal year). In addition, the Company recorded interest income of ¥3,240 thousand, foreign exchange gains of ¥17,373 thousand, and other items as non-operating income, as well as interest expenses of ¥8,837 thousand, amortization of restricted stock remuneration of ¥2,571 thousand, share issuance costs of ¥2,248 thousand, and other items as non-operating expenses, resulting in ordinary loss of ¥760,604 thousand (ordinary loss of ¥1,311,654 thousand in the same period of the previous fiscal year). As a result, net loss was ¥762,153 thousand (net loss of ¥1,313,230 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 ¥4,510,606 thousand (1% decrease compared with the end of the previous fiscal year), owing partly to a decrease in cash and deposits. Liabilities were ¥1,253,229 thousand (125.4% increase compared with the end of the previous fiscal year), owing partly to an increase in short-term loans payable. Net assets were ¥3,257,377 thousand (18.6% 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 distribution partnership agreement for OBP-301, achieving the development event of LINE-1 inhibitor OBP-601 by Transposon, and the company's IPO, M&A and other corporate action that generates milestone revenue payments. The product sales revenue from OBP-301, which we aim to launch in Japan in 2026, will also fluctuate greatly depending on factors such as market development. Furthermore, our financial results fluctuate depending on terms and conditions of international alliance agreements of OBP-301.

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, 2025	As of June 30, 2026
Assets		
Current assets		
Cash and deposits	3,674,717	3,186,837
Accounts receivable – trade	31,306	582,478
Supplies	3,916	3,592
Advance payments – other	333,740	169,226
Prepaid expenses	61,520	40,905
Accounts receivable – other	302,276	445,073
Consumption taxes receivable	39,907	15,967
Short-term loans receivable from subsidiaries and associates	46,959	16,239
Other	10	10
Total current assets	4,494,353	4,460,329
Non-current assets		
Property, plant and equipment		
Buildings	3,306	3,306
Accumulated depreciation	(3,306)	(3,306)
Buildings, net	–	–
Machinery and equipment	924	924
Accumulated depreciation	(924)	(924)
Machinery and equipment, net	–	–
Tools, furniture and fixtures	35,734	35,361
Accumulated depreciation	(35,734)	(34,193)
Tools, furniture and fixtures, net	–	1,167
Total property, plant and equipment	–	1,167
Investments and other assets		
Shares of subsidiaries and associates	20,936	20,936
Investments in capital	100	100
Lease and guarantee deposits	26,277	24,860
Long-term prepaid expenses	14,208	3,209
Other	4	4
Total investments and other assets	61,525	49,109
Total non-current assets	61,525	50,277
Total assets	4,555,879	4,510,606

(Thousand yen)

	As of December 31, 2025	As of June 30, 2026
Liabilities		
Current liabilities		
Short-term loans payable	233,332	687,222
Lease obligations	10,311	9,499
Accounts payable – other	65,232	71,872
Accrued expenses	26,238	181,350
Income taxes payable	15,025	12,129
Contract liabilities	110,000	110,000
Deposits received	10,580	68,862
Total current liabilities	470,721	1,140,936
Non-current liabilities		
Long-term loans payable	66,656	97,214
Lease obligations	9,720	5,393
Provision for retirement benefits	8,812	9,685
Total non-current liabilities	85,188	112,293
Total liabilities	555,909	1,253,229
Net assets		
Shareholders' equity		
Capital stock	4,366,132	4,002,558
Capital surplus		
Legal capital surplus	1,621,460	10,250
Other capital surplus	62,763	0
Total capital surpluses	1,684,224	10,250
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(2,058,049)	(762,153)
Total retained earnings	(2,058,049)	(762,153)
Treasury shares	(17)	(321)
Total shareholders' equity	3,992,289	3,250,334
Share acquisition rights	7,680	7,043
Total net assets	3,999,969	3,257,377
Total liabilities and net assets	4,555,879	4,510,606

(2) Semi-annual Statements of Income

(Thousand yen)

	For the six months ended June 30, 2025	For the six months ended June 30, 2026
Net sales	28,546	503,090
Cost of sales	–	–
Gross profit	28,546	503,090
Selling, general and administrative expenses	1,295,673	1,270,697
Operating loss	(1,267,127)	(767,606)
Non-operating income		
Interest income	1,824	3,240
Dividend income	3	3
Foreign exchange gains	–	17,373
Other	27	40
Total non-operating income	1,854	20,658
Non-operating expenses		
Interest expenses	2,289	8,837
Amortization of restricted stock remuneration	5,030	2,571
Foreign exchange losses	39,061	–
Share issuance costs	–	2,248
Total non-operating expenses	46,381	13,656
Ordinary loss	(1,311,654)	(760,604)
Loss before income taxes	(1,311,654)	(760,604)
Income taxes – current	1,576	1,549
Total income taxes	1,576	1,549
Loss	(1,313,230)	(762,153)

(3) Semi-annual Statements of Cash Flows

(Thousand yen)

	For the six months ended June 30, 2025	For the six months ended June 30, 2026
Cash flows from operating activities		
Loss before income taxes	(1,311,654)	(760,604)
Depreciation	52	73
Amortization of restricted stock remuneration	5,030	2,571
Share-based remuneration expenses	10,308	23,875
Increase (decrease) in provision for retirement benefits	798	873
Interest and dividend income	(1,827)	(3,243)
Interest expenses	2,289	8,837
Share issuance costs	–	2,248
Foreign exchange losses (gains)	27,344	(2,330)
Decrease (increase) in notes and accounts receivable – trade	(28,962)	(551,172)
Decrease (increase) in inventories	(81)	323
Decrease (increase) in prepaid expenses	(8,446)	5,681
Decrease (increase) in accounts receivable – other	(86,074)	(143,369)
Decrease (increase) in consumption taxes refund receivable	27,457	23,939
Decrease (increase) in advance payments – other	326,188	164,514
Increase (decrease) in accounts payable – other	28,233	7,010
Increase (decrease) in accrued expenses	(1,382)	155,111
Other, net	(20,818)	58,063
Subtotal	(1,031,542)	(1,007,596)
Interest and dividend income received	859	3,842
Interest expenses paid	(2,744)	(9,722)
Income taxes refund (paid)	(3,861)	(3,833)
Net cash provided by (used in) operating activities	(1,037,289)	(1,017,309)
Cash flows from investing activities		
Purchase of property, plant and equipment	(1,114)	(1,241)
Payments of leasehold and guarantee deposits	(3,925)	–
Proceeds from collection of loans receivable	–	31,742
Proceeds from refund of lease and guarantee deposits	–	1,024
Net cash provided by (used in) investing activities	(5,040)	31,525
Cash flows from financing activities		
Net increase (decrease) in short-term loans payable	–	440,000
Proceeds from long-term loans payable	100,000	100,000
Repayments of long-term loans payable	(52,774)	(55,552)
Repayments of lease obligations	(5,072)	(5,138)
Proceeds from issuance of common shares	–	17,616
Purchase of treasury shares	–	(303)
Net cash provided by (used in) financing activities	42,153	496,622
Effect of exchange rate change on cash and cash equivalents	(23,217)	1,282
Net increase (decrease) in cash and cash equivalents	(1,023,393)	(487,879)
Cash and cash equivalents at beginning of period	2,165,918	3,429,561
Cash and cash equivalents at end of period	1,142,525	2,941,682

(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)

The Company received payment from the exercise of share acquisition rights during the six months ended June 30, 2026. In addition, based on the resolution by the Annual General Meeting of Shareholders held on March 24, 2026, a capital reduction became effective on May 31, 2026, and the Company reduced capital stock by ¥373,824 thousand and legal capital surplus by ¥1,621,460 thousand and transferred them to other capital surplus. Thereafter, the Company reduced the entire amount of other capital surplus of ¥2,058,049 thousand and transferred it to retained earnings brought forward to compensate the deficit. As a result, at the end of the period, capital stock was ¥4,002,558 thousand and legal capital surplus was ¥10,250 thousand.

(Segment information, etc.)

[Segment information]

I. 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.

II. For the six months ended June 30, 2026

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, 2025	For the six months ended June 30, 2026
Goods / Services transferred at a point in time	28,546	503,090
Goods / Services transferred over time	—	—
Revenue from contracts with customers	28,546	503,090
Revenue from other sources	—	—
Net sales to outside customers	28,546	503,090

(Significant subsequent events)

Capital increase through exercise of share acquisition rights

During the period starting on July 1, 2026 and ending on July 31, 2026, a portion of the 13th and 14th series Share Acquisition Rights was exercised as follows:

(1) Class and number of shares issued	146,000 shares of common stock
(2) Number of units of share acquisition rights exercised	1,460 units
(3) Total amount exercised	102,752 thousand yen
(4) Amount of increase in capital stock	52,106 thousand yen
(5) Amount of increase in legal capital surplus	52,106 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 730 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 July 31, 2026 was 29,465,700 shares, capital stock was 4,054,664 thousand yen, and legal capital surplus was 62,356 thousand yen.

3. Supplemental Information

(1) Research and Development Activities

Research and development expenses of the Company in the six months ended June 30, 2026 totaled ¥766,164 thousand for the drug discovery business. The status of research and development activities during the six months ended June 30, 2026 is as follows.

(1) Research and development structure

As of June 30, 2026, 27 persons belonged to the research and development department, accounting for 60.0% 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, which obtained its manufacturing and marketing approval as a regenerative medicine product for esophageal cancer in June 2026—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 and obtained its manufacturing and marketing approval from the Ministry of Health, Labour and Welfare as a regenerative medicine product for esophageal cancer in June 2026. The approval was granted as a "full marketing approval," rather than a conditional and time-limited approval. In addition, as a full marketing approval, OBP-301 is not required to undergo any post-marketing clinical trials. A plenary meeting of the Central Social Insurance Medical Council was held in August 2026, and the drug price of OBP-301 was approved at ¥3,102,489 (¥9,307,467/patient).

As an indication expansion study for OBP-301 in Japan following the indication in combination with radiation therapy for esophageal cancer, the Company submitted in June 2026 a clinical trial notification for Phase Ib / IIa clinical trials in combination with chemoradiotherapy for lower rectal and anal cancers. Administration under the study is expected to begin in the fiscal year ending December 31, 2026.

Meanwhile, regarding development overseas, 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 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, for the Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer, which was conducted by NRG Oncology, a cancer research organization in the U.S., the interim results were presented at the ASCO-GI (American Society of Clinical Oncology Gastrointestinal Cancers Symposium) in January 2025 and the interim results of the study were published in an overseas medical journal.

Regarding our domestic business, associated with the manufacturing and marketing approval, the Company received a milestone revenue payment and advances from FUJIFILM Toyama Chemical, the marketing partner, in July 2026. In addition, we have established a supply chain for OBP-301 from Henogen SA, the manufacturer, via MITSUI-SOKO HOLDINGS Co., Ltd. (hereinafter "MITSUI-SOKO HOLDINGS"), responsible for logistics such as storage and packaging in Japan, and through FUJIFILM Toyama Chemical, the marketing partner, to medical institutions. We are working to extend the shelf life of OBP-301 to enhance flexibility in inventory management for preparation for the launch.

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. We will continue to advance overseas business development and plan to expand the markets for OBP-301 in Japan and overseas.

As for intellectual property, in May 2026, an extension of the scope of patent protection was granted for the administration of oncolytic adenovirus through an endoscope, for which a patent had already been granted in Japan. In addition, we received a communication of the intention to grant a patent for the administration through an endoscope in Europe. These patents are not limited to OBP-301, but also cover OBP-702 and oncolytic adenovirus of other companies. The duration of patents is until May 2040.

OBP-301 has been undergoing the following four clinical trials in Japan and overseas, including the one for which manufacturing and marketing approval has been obtained and the one for which 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
iv) Phase Ib / IIa clinical trials in combination with chemoradiotherapy for lower rectal and anal cancers

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

The Phase II clinical trial in combination with radiation therapy for esophageal cancer (OBP101JP trial) was conducted based on the "SAKIGAKE designation" of April 2019 at 17 clinical trial sites around Japan, and we obtained its manufacturing and marketing approval as a regenerative medicine product for esophageal cancer in June 2026. The approval was granted as a "full marketing approval" and does not require any post-marketing clinical trials. Associated with the manufacturing and marketing approval, the Company received a milestone revenue payment and advances from FUJIFILM Toyama Chemical, the marketing partner, in July 2026. A plenary meeting of the Central Social Insurance Medical Council was held in August 2026, and the drug price of OBP-301 was approved at ¥3,102,489 (¥9,307,467/patient).

In order to ensure a smooth supply of OBP-301, the Company completed the enclosure of the first commercial lot of the formulated drug into individual packaging boxes at MITSUI-SOKO HOLDINGS, the domestic manufacturing site. The Company plans to ship the first commercial lot with a shelf life of 18 months. OBP-301 shipped by the Company will be provided to medical facilities by medical products companies through FUJIFILM Toyama Chemical, with which the Company concluded a sales collaboration agreement in February 2024.

In addition, the second commercial lot of the drug has been formulated and manufactured at Henogen SA and is ready to be imported into Japan. The Company plans to confirm its stability data for a twenty-four-month period in the second half of the fiscal year ending December 31, 2026. Going forward, the Company will work to extend the shelf life to enhance flexibility in inventory management of OBP-301.

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 "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 patient enrolment has been progressing.

At the International Oncolytic Virus Conference (IOVC) held in Iceland in April 2026, results were reported on the long-term survival rate in the Phase II clinical trial of third-line treatment in combination with pembrolizumab for gastric cancer, for which patient enrolment had been completed prior to the above clinical trial.

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

Regarding the "Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer," NRG Oncology, one of the world's largest and authoritative clinical trials groups, supported by the National Cancer Institute in the U.S., has been leading the trial. Administration began in December 2021 with the purpose of investigating the safety and efficacy of using OBP-301 in combination with chemoradiotherapy, and 15 patients were registered. The interim results of the study were published in International Journal of Radiation Oncology - Biology - Physics.

OBP-301 has been designated as an orphan drug for esophageal cancer in the U.S., and this clinical trial was 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.

iv) Phase Ib / IIa clinical trials in combination with chemoradiotherapy for lower rectal and anal cancers

Regarding the "Phase Ib / IIa clinical trials in combination with chemoradiotherapy for lower rectal and anal cancers," the Company submitted a clinical trial notification to the Pharmaceuticals and Medical Devices Agency (PMDA) in June 2026. The trials are pilot trials to assess the safety and efficacy by administering OBP-301 in combination with preoperative chemoradiotherapy. In assessing the efficacy, the local tumor-shrinking effect will be judged after the completion of the combined administration of preoperative chemotherapy and OBP-301. The Company plans to begin administration under the trials in the fiscal year ending December 31, 2026.

2) Activities related to OBP-601 (censavudine), a LINE-1 inhibitor

From 2010 to 2014, OBP-601 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. Furthermore, it was announced that the Advanced Research Projects Agency for Health (hereinafter "ARPA-H") in the U.S. awarded up to $22 million (hereinafter the "Award") to support research and development programs aimed at extending healthy life expectancy using OBP-601, under the PROSPR (Proactive Solutions for Prolonging Resilience) program. ARPA-H plans to provide funds from the Award to Transposon and participating research institutions based on research progress and expenses incurred. Transposon 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 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. Transposon plans to begin Phase III clinical trials for PSP in 2026, after financing is completed. 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. 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. Transposon plans to begin Phase II / III clinical trials for ALS by utilizing the HEALEY ALS Platform Trial in 2026.

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. The Alzheimer's Drug Discovery Foundation (hereinafter the "ADDF") has determined that OBP-601 is promising for the treatment of Alzheimer's disease 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 2026.

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.

v) Research and development aimed at extending healthy life expectancy

OBP-601 was selected by ARPA-H for research and development support (the "Award"), amid growing attention to the relationship between increases in inflammation due to aging and activation of LINE-1. The Award of up to $22 million will be provided to Transposon and participating research institutions to support research and development programs aimed at extending healthy life expectancy utilizing OBP-601's potential to promote healthy aging. Transposon and the participating research institutions will advance this research, with a view to future clinical application.

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 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. The Company expects Okayama University to begin an investigator-initiated clinical trial of OBP-702 for the treatment of pancreatic cancer in 2026.

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, OBP-2011 assumes a nucleocapsids inhibit, 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. 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, as acquiring the large number of images required for image learning has taken longer than initially planned. We have lowered the priority of these activities in order to concentrate management resources on OBP-301.

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, the use inventions of OBP-801 related to “suppression of filtering bleb fibrosis after glaucoma surgery” and “age-related macular degeneration” received decisions to grant patents in Japan in July 2024. We have lowered the priority of these activities in order to concentrate management resources on OBP-301.

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	Full marketing approval
		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)
	Lower rectal and anal cancers	Chemoradiotherapy	Japan	Phase Ib / IIa
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