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Non-consolidated Financial Results for the Fiscal Year Ended December 31, 2024 [Japanese GAAP]

February 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 Annual General Meeting of Shareholders: March 27, 2025
Scheduled date of commencing dividend payments: —
Scheduled date of filing annual securities report: March 28, 2025
Availability of supplementary briefing material on financial results: No
Schedule of financial results briefing session: Scheduled (for analysts)

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

1. Financial Results for the Fiscal Year Ended December 31, 2024 (January 1, 2024 to December 31, 2024)

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

	Net sales		Operating profit		Ordinary profit		Profit	
Fiscal year ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
December 31, 2024	31	(50.2)	(1,681)	-	(1,663)	-	(1,684)	-
December 31, 2023	63	(93.5)	(1,929)	-	(1,913)	-	(1,938)	-

	Basic earnings per share	Diluted earnings per share	Rate of return on equity	Ordinary profit to total assets	Operating profit to net sales
Fiscal year ended	Yen	Yen	%	%	%
December 31, 2024	(77.17)	-	(80.2)	(63.5)	-
December 31, 2023	(108.92)	-	(107.4)	(81.6)	-

(Reference) Equity in earnings of affiliates: Fiscal year ended December 31, 2024: ¥- million
Fiscal year ended December 31, 2023: ¥- million

(2) Financial Position

	Total assets	Net assets	Equity ratio	Net assets per share
	Million yen	Million yen	%	Yen
As of December 31, 2024	3,198	2,752	85.8	110.40
As of December 31, 2023	2,040	1,474	71.5	74.35

(Reference) Equity: As of December 31, 2024: ¥2,744 million
As of December 31, 2023: ¥1,459 million

(3) Cash Flows

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at end of period
Fiscal year ended	Million yen	Million yen	Million yen	Million yen
December 31, 2024	(2,020)	(4)	2,879	2,165
December 31, 2023	(1,336)	(5)	1,142	1,287

2. Dividends

	Annual dividends					Total dividends	Payout ratio	Dividends to net assets
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total			
	Yen	Yen	Yen	Yen	Yen	Million yen	%	%
Fiscal year ended December 31, 2023	-	0.00	-	0.00	0.00	-	-	-
Fiscal year ended December 31, 2024	-	0.00	-	0.00	0.00	-	-	-
Fiscal year ending December 31, 2025 (Forecast)	-	0.00	-	0.00	0.00		-	

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. Overview of Business Results, etc. (4) Future Outlook" on page 3 of the supplementary material.

*** Notes:**

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

(2) Total number of issued shares (common shares)

1) Total number of issued shares at the end of the period (including treasury shares):
- December 31, 2024: 24,961,600 shares
- December 31, 2023: 19,717,100 shares

2) Total number of treasury shares at the end of the period:
- December 31, 2024: 101,238 shares
- December 31, 2023: 88,738 shares

3) Average number of shares during the period:
- Fiscal year ended December 31, 2024: 21,831,246 shares
- Fiscal year ended December 31, 2023: 17,797,360 shares

* These financial results are outside the scope of audit 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, please see “1. Overview of Business Results, etc. (4) Future Outlook” on page 3 of the supplementary material.

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1. Overview of Business Results, etc.

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

The Japanese economy during the fiscal year ended December 31, 2024 showed signs of recovery, with the Bank of Japan deciding to raise interest rates for the first time in 17 years, against a backdrop of factors such as the pick-up in inbound tourist demand and historic wage hikes, mainly at major companies. On the other hand, the unstable situation in the global economy is expected to persist, with the Ukraine war becoming protracted and uncertainty rising due to changes of government in various countries, including the U.S. presidency.

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," thus striving to increase managerial efficiency and actively expand research, development and licensing activities.

In particular, the Company is promoting research, development, and licensing activities with a focus on OBP-301 virotherapy for cancer. Having been granted "SAKIGAKE designation" for regenerative medicine products for OBP-301 by the Ministry of Health, Labour and Welfare, the Company completed a "Phase II clinical trial in combination with radiation therapy for esophageal cancer (OBP101JP trial)." The results of this clinical trial were presented in October 2024 at the 62nd Annual Meeting of the Japan Society of Clinical Oncology held in Fukuoka. Following repeated discussions with the Pharmaceuticals and Medical Devices Agency (hereinafter "PMDA") regarding the application for approval of OBP-301, it was agreed to make the transition to the SAKIGAKE comprehensive evaluation consultation. We will begin the SAKIGAKE comprehensive evaluation consultation in the first half of 2025. After undergoing an examination of the contents, including the post-marketing clinical trial plan, we plan to submit an application for approval in the fiscal year ending December 31, 2025.

Regarding our domestic business, in February 2024, we signed an agreement with FUJIFILM Toyama Chemical Co., Ltd. (hereinafter "FUJIFILM Toyama Chemical") to collaborate in OBP-301 sales and established a supply chain for OBP-301 from Henogen SA (in the Thermo Fisher Group, Belgium), the manufacturer, to medical institutions. We are now promoting various consultations regarding a sales system after products are launched in the market. Furthermore, we have applied to the Tokyo Metropolitan Government to obtain approval for the manufacture and sale of regenerative medical products.

Meanwhile, in the U.S., we have established a joint development system for OBP-301 and pembrolizumab, and the Company and Merck Sharp & Dohme LLC. (hereinafter "MSD") equally share research and development expenses for a Phase II investigator-initiated clinical trial for the treatment of gastric cancer in patients who are receiving second-line treatment. The safety and preliminary efficacy findings of the Phase I investigator-initiated clinical trial using OBP-301 in combination with chemoradiotherapy for esophageal cancer were presented at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium in January 2025. In addition, in December 2024, we concluded a license agreement with Medigen Biotechnology Corp. (hereinafter "Medigen") in Taiwan for sales rights in Taiwan.

Concerning LINE-1 inhibitor OBP-601, Transposon Therapeutics, Inc. (hereinafter "Transposon") is conducting clinical trials at its own full expense based on a license agreement.

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

For the fiscal year ended December 31, 2024, net sales were ¥31,384 thousand (net sales of ¥63,038 thousand in the previous fiscal year), and operating loss was ¥1,681,403 thousand (operating loss of ¥1,929,986 thousand in the previous fiscal year). In addition, the Company recorded foreign exchange gains of ¥43,775 thousand, and other items as non-operating income, as well as share acquisition rights issuance costs of ¥7,202 thousand, share issuance costs of ¥10,394 thousand, and other items as non-operating expenses. Ordinary loss was ¥1,663,911 thousand (ordinary loss of ¥1,913,816 thousand in the previous fiscal year). The Company also recorded an impairment loss of ¥17,104 thousand on the devices, etc., used in the warehouses where the Company stores OBP-301, as an extraordinary loss. As a result, net loss was ¥1,684,778 thousand (net loss of ¥1,938,505 thousand in the previous fiscal year).

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

1) Status of Assets, Liabilities and Net Assets

Assets at the end of the fiscal year under review were ¥3,198,858 thousand (56.8% increase compared with the end of the previous fiscal year), owing partly to an increase in cash and deposits. Liabilities were ¥446,649 thousand (21.2% decrease compared with the end of the previous fiscal year), owing partly to a decrease in

accounts payable - other. Net assets were ¥2,752,209 thousand (86.7% increase compared with the end of the previous fiscal year), owing to capital increase through issuance of new shares, loss incurred and other factors.

2) Status of Cash Flows

Cash and cash equivalents at the end of the fiscal year under review were ¥2,165,918 thousand (68.2% increase compared with the end of the previous fiscal year). Cash flows for the fiscal year under review were as follows.

(Cash flows from operating activities)

Net cash flows used in operating activities were ¥2,020,088 thousand (a cash outflow of ¥1,336,922 thousand in the previous fiscal year). This is primarily attributable to loss before income taxes of ¥1,681,015 thousand and impairment losses of ¥17,104 thousand, an increase in advance payments – other of ¥198,366 thousand, an increase in accounts receivable – other of ¥50,506 thousand, and a decrease in accounts payable - other of ¥141,352 thousand.

(Cash flows from investing activities)

Net cash flows used in investing activities were ¥4,705 thousand (a cash outflow of ¥5,392 thousand in the previous fiscal year). This is primarily attributable to purchase of property, plant and equipment of ¥3,519 thousand.

(Cash flows from financing activities)

Net cash flows provided by financing activities were ¥2,879,444 thousand (a cash inflow of ¥1,142,542 thousand in the previous fiscal year). This is primarily attributable to proceeds from issuance of common shares of ¥2,890,817 thousand, proceeds from long-term loans payable of ¥100,000 thousand, repayments of long-term loans payable of ¥94,444 thousand and repayments of lease obligations of ¥11,925 thousand.

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

	Fiscal year ended December 31, 2022	Fiscal year ended December 31, 2023	Fiscal year ended December 31, 2024
Equity ratio (%)	81.2	71.5	85.8
Equity ratio based on fair value (%)	344.4	545.4	402.6
Interest-bearing liabilities to cash flows (Note 4)	—	—	—
Interest coverage ratio (Note 4)	—	—	—

Equity ratio: Equity/Total assets
Equity ratio based on fair value: Total market value of shares/Total assets
Interest-bearing liabilities to cash flows: Interest-bearing liabilities /Cash flows
Interest coverage ratio: Cash flows/Interest payments

(Note 1) Total market value of shares was calculated by multiplying the closing price on the fiscal year-end date by the number of outstanding shares on the fiscal year-end date (excluding treasury shares).
(Note 2) Operating cash flows are used as cash flows.
(Note 3) Interest-bearing liabilities include all liabilities recorded on the balance sheets for which interests are paid.
(Note 4) Figures are not presented as operating cash flows were negative.

(4) Future Outlook

The Company still has a small stable revenue base, and our financial results fluctuate greatly depending on 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 that company's IPO, M&A and other corporate action that generates milestone revenue payments.

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

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

As a research and development based venture, the Company has focused on upfront investments of business capital, etc., and has yet to distribute profits. However, the Company recognizes the return of profits to shareholders to be an important issue for management and will determine its dividend policy that takes the operating results of each fiscal year into account, while considering further strengthening of the management

foundation and the enhancement of internal reserves in preparation for further proactive business development. In accordance with this basic policy, dividend distributions are not scheduled for the fiscal year under review or the next fiscal year.

2. Management Policies

(1) Basic Policy on Management

The Company conducts a research- and development-oriented business as a biotech company for drug discovery and promotes the development and commercialization of novel drugs for cancer virotherapy, drugs for the treatment of serious infectious diseases and other drugs. In particular, we aim to grow as a virus drug discovery company focusing on the fields of "virotherapy for cancer," primarily the oncolytic virus OBP-301 and the next-generation oncolytic virus OBP-702, as well as "drugs for the treatment of serious viral infectious diseases," mainly OBP-2011 for the treatment of viral infectious diseases. Furthermore, OBP-601, a drug which utilizes the mechanism of a nucleoside reverse transcriptase inhibitor and that was developed as a treatment for HIV infection, is being repositioned as a LINE-1 inhibitor, and is being developed by Transposon under license as a treatment for intractable neurological diseases.

Until now, the Company's business model has been to develop drug pipelines up to the initial clinical trial stage, and then license the pipelines to pharmaceutical companies for further development and marketing in exchange for contractual lump-sum payments, milestone revenue, royalty revenue, etc. Going forward, however, in addition to the license-type business model described above, the Company will pursue the development of OBP-301 in Japan according to a pharmaceutical company-type business model, in which we obtain the required manufacturing and marketing approvals by ourselves.

We intend to move away from a business model based solely on license income that depends on the management policies of major pharmaceutical companies, and transform the Company itself into a hybrid business model that combines a "pharmaceutical company-type business model that provides a steady revenue stream by supplying pharmaceutical products as a manufacturer and distributor" and a "license-type business model."

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

(2) Target Business Indicators

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

(3) Medium- to Long-term Management Strategies

The basic strategy of the Company involves achieving efficient progress from pre-clinical to clinical trials and building a fabless management model utilizing outsourcing, with focus placed on hiring and cultivating personnel specializing in project management of drug discovery research and development. The Company's management strategy has been to maximize the value of its pipeline by achieving rapid progression to the next stage in development, conclude licensing agreements with major pharmaceutical companies and biotech companies on better conditions, and use the funds from licensing partners to advance the development of new drugs. Moving forward, we would like to develop not only such a license-based management strategy, but also a pharmaceutical company-type business scheme which involves obtaining approval for new drugs in-house and selling them through distribution partners.

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

(4) Issues to be Addressed

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

a. Promoting the corporate philosophy

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

b. Securing and cultivating personnel

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

c. Strengthening research and development structures

The research and development of the Company has covered the whole process from the search and invention of prospective pharmaceuticals to pre-clinical trials and initial clinical trials (i.e., proof of concept). The main role of the Company has been to act as a bridge between the pre-clinical and clinical stages (i.e., translational research), and conduct manufacturing and quality control of investigational drugs to promote these research and developments. In addition to these activities, we will also strengthen our pharmaceutical system, which handles liaison work with the Ministry of Health, Labour and Welfare, and our quality assurance operations, which manage and control manufacturing and sales. Therefore, it is an important issue to secure and cultivate personnel who take responsibility as project leaders engaging primarily in planning and progress management for research and development, as well as persons experienced in the pharmaceutical business and quality assurance operations. The Company has its research and development system both in Japan and overseas. The Company strives to enhance collaboration with the clinical development department of a wholly-owned subsidiary Oncolys USA Inc. (hereinafter "Oncolys USA"). Furthermore, along with incorporating advanced technologies and improving technological levels through joint research and development with global medical and research institutions, the Company actively utilizes outsourcing partners and endeavors to construct low-cost and high-level research and development structures.

d. Strengthening business development department

The Company defines its business fields as the field of virotherapy for cancer using genetically modified virus formulations and therapeutic drugs for serious viral infectious diseases, aiming for the commercialization of exceedingly unique virus drug discovery for this industry. Therefore, the Company will secure and cultivate talent that possesses both business skills and abundant scientific knowledge and strengthen its network with pharmaceutical companies around the world. Furthermore, by enhancing collaboration with our subsidiary in the United States, Oncolys USA, the Company aims to generate numerous joint development and licensing

opportunities with pharmaceutical companies overseas and construct business development structures that can contribute to increasing its cash flows.

e. Outsourcing strategies

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

3. Basic Stance Concerning Choice of Accounting Standards

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

4. Financial Statements and Primary Notes
(1) Balance Sheets

(Thousand yen)

	As of December 31, 2023	As of December 31, 2024
Assets		
Current assets		
Cash and deposits	1,532,844	2,411,001
Supplies	5,342	4,578
Advance payments – other	282,602	480,969
Prepaid expenses	33,338	53,448
Accounts receivable – other	51,781	102,417
Consumption taxes receivable	49,964	45,829
Other	9	–
Total current assets	1,955,883	3,098,244
Non-current assets		
Property, plant and equipment		
Buildings	3,128	3,128
Accumulated depreciation	(3,128)	(3,128)
Buildings, net	–	–
Machinery and equipment	924	924
Accumulated depreciation	(924)	(924)
Machinery and equipment, net	–	–
Tools, furniture and fixtures	66,967	67,782
Accumulated depreciation	(66,967)	(67,782)
Tools, furniture and fixtures, net	–	–
Total property, plant and equipment	–	–
Investments and other assets		
Shares of subsidiaries and associates	20,936	20,936
Investments in capital	100	100
Long-term loans receivable from subsidiaries and associates	42,549	47,445
Lease and guarantee deposits	20,990	22,174
Long-term prepaid expenses	135	9,955
Other	4	4
Total investments and other assets	84,714	100,614
Total non-current assets	84,714	100,614
Total assets	2,040,598	3,198,858

(Thousand yen)

	As of December 31, 2023	As of December 31, 2024
Liabilities		
Current liabilities		
Short-term loans payable	127,776	127,776
Lease obligations	7,565	10,177
Accounts payable – other	193,354	52,287
Accrued expenses	19,119	20,451
Income taxes payable	18,844	31,885
Deposits received	11,870	9,812
Total current liabilities	378,531	252,390
Non-current liabilities		
Long-term loans payable	161,100	166,656
Lease obligations	18,729	20,031
Provision for retirement benefits	8,140	7,570
Total non-current liabilities	187,969	194,258
Total liabilities	566,500	446,649
Net assets		
Shareholders' equity		
Capital stock	3,623,165	5,108,160
Capital surplus		
Legal capital surplus	1,209,590	2,694,489
Total capital surpluses	1,209,590	2,694,489
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(3,373,199)	(5,057,978)
Total retained earnings	(3,373,199)	(5,057,978)
Treasury shares	(142)	(142)
Total shareholders' equity	1,459,413	2,744,529
Share acquisition rights	14,683	7,680
Total net assets	1,474,097	2,752,209
Total liabilities and net assets	2,040,598	3,198,858

(2) Statements of Income

(Thousand yen)

	For the fiscal year ended December 31, 2023	For the fiscal year ended December 31, 2024
Net sales	63,038	31,384
Cost of sales		
Cost of service	32,433	–
Beginning finished goods	8,434	–
Total	8,434	–
Finished goods transfer to other account	8,434	–
Ending finished goods	–	–
Gross profit	30,604	31,384
Selling, general and administrative expenses	1,960,591	1,712,787
Operating loss	(1,929,986)	(1,681,403)
Non-operating income		
Interest income	1,475	2,145
Dividend income	3	5
Subsidy income	2,953	–
Foreign exchange gains	27,598	43,775
Other	177	40
Total non-operating income	32,208	45,966
Non-operating expenses		
Interest expenses	3,602	4,597
Amortization of restricted stock remuneration	629	6,205
Share acquisition rights issuance costs	3,029	7,202
Share issuance costs	8,777	10,394
Other	–	73
Total non-operating expenses	16,038	28,473
Ordinary loss	(1,913,816)	(1,663,911)
Extraordinary income		
Gain on sale of non-current assets	136	–
Total extraordinary income	136	–
Extraordinary losses		
Impairment loss	21,898	17,104
Total extraordinary losses	21,898	17,104
Loss before income taxes	(1,935,578)	(1,681,015)
Income taxes – current	2,926	3,763
Total income taxes	2,926	3,763
Loss	(1,938,505)	(1,684,778)

(3) Statements of Changes in Equity

For the fiscal year ended December 31, 2023

(Thousand yen)

	Shareholders' equity						
	Capital stock	Capital surplus		Retained earnings		Treasury shares	Total shareholders' equity
		Legal capital surplus	Total capital surpluses	Other retained earnings	Total retained earnings		
				Retained earnings brought forward			
Balance at beginning of current period	3,000,000	586,425	586,425	(1,434,694)	(1,434,694)	(142)	2,151,589
Changes of items during period							
Issuance of new shares	623,165	623,165	623,165				1,246,330
Loss				(1,938,505)	(1,938,505)		(1,938,505)
Net changes of items other than shareholders' equity							
Total changes of items during period	623,165	623,165	623,165	(1,938,505)	(1,938,505)	–	(692,175)
Balance at end of current period	3,623,165	1,209,590	1,209,590	(3,373,199)	(3,373,199)	(142)	1,459,413

	Share acquisition rights	Total net assets
Balance at beginning of current period	7,680	2,159,269
Changes of items during period		
Issuance of new shares		1,246,330
Loss		(1,938,505)
Net changes of items other than shareholders' equity	7,003	7,003
Total changes of items during period	7,003	(685,172)
Balance at end of current period	14,683	1,474,097

For the fiscal year ended December 31, 2024

	Shareholders' equity						
	Capital stock	Capital surplus		Retained earnings		Treasury shares	Total shareholders' equity
		Legal capital surplus	Total capital surpluses	Other retained earnings	Total retained earnings		
				Retained earnings brought forward			
Balance at beginning of current period	3,623,165	1,209,590	1,209,590	(3,373,199)	(3,373,199)	(142)	1,459,413
Changes of items during period							
Issuance of new shares	1,484,995	1,484,898	1,484,898				2,969,893
Loss				(1,684,778)	(1,684,778)		(1,684,778)
Net changes of items other than shareholders' equity							
Total changes of items during period	1,484,995	1,484,898	1,484,898	(1,684,778)	(1,684,778)	–	1,285,115
Balance at end of current period	5,108,160	2,694,489	2,694,489	(5,057,978)	(5,057,978)	(142)	2,744,529

	Share acquisition rights	Total net assets
Balance at beginning of current period	14,683	1,474,097
Changes of items during period		
Issuance of new shares		2,969,893
Loss		(1,684,778)
Net changes of items other than shareholders' equity	(7,003)	(7,003)
Total changes of items during period	(7,003)	1,278,112
Balance at end of current period	7,680	2,752,209

(4) Statements of Cash Flows

(Thousand yen)

	For the fiscal year ended December 31, 2023	For the fiscal year ended December 31, 2024
Cash flows from operating activities		
Loss before income taxes	(1,935,578)	(1,681,015)
Depreciation	2,286	815
Impairment loss	21,898	17,104
Amortization of restricted stock remuneration	629	6,205
Share-based remuneration expenses	9,433	19,426
Increase (decrease) in provision for retirement benefits	391	(569)
Interest and dividend income	(1,478)	(2,150)
Interest expenses	3,602	4,597
Share acquisition rights issuance costs	3,029	7,202
Share issuance costs	8,777	10,394
Foreign exchange losses (gains)	(24,090)	(28,429)
Decrease (increase) in inventories	18,907	764
Decrease (increase) in prepaid expenses	4,437	3,943
Decrease (increase) in accounts receivable – other	123,411	(50,506)
Decrease (increase) in consumption taxes refund receivable	28,015	5,575
Decrease (increase) in advance payments – other	223,713	(198,366)
Increase (decrease) in accounts payable – other	132,727	(141,352)
Other, net	20,812	11,504
Subtotal	(1,359,074)	(2,014,856)
Interest and dividend income received	616	2,049
Interest expenses paid	(3,836)	(4,337)
Income taxes refund (paid)	25,372	(2,944)
Net cash provided by (used in) operating activities	(1,336,922)	(2,020,088)
Cash flows from investing activities		
Payments into time deposits	(1)	(1)
Purchase of property, plant and equipment	(5,686)	(3,519)
Proceeds from sale of property, plant and equipment	136	–
Proceeds from refund of lease and guarantee deposits	159	240
Payments of leasehold and guarantee deposits	–	(1,424)
Net cash provided by (used in) investing activities	(5,392)	(4,705)
Cash flows from financing activities		
Proceeds from long-term loans payable	100,000	100,000
Repayments of long-term loans payable	(194,444)	(94,444)
Repayments of lease obligations	(4,540)	(11,925)
Proceeds from issuance of common shares	1,223,450	2,890,817
Proceeds from issuance of share acquisition rights	18,076	–
Payments for issuance of share acquisition rights	–	(5,002)
Net cash provided by (used in) financing activities	1,142,542	2,879,444
Effect of exchange rate change on cash and cash equivalents	21,334	23,504
Net increase (decrease) in cash and cash equivalents	(178,437)	878,155
Cash and cash equivalents at beginning of period	1,466,201	1,287,763
Cash and cash equivalents at end of period	1,287,763	2,165,918

(5) Notes to Financial Statements

(Notes on going concern assumption)

There is no relevant information.

(Significant accounting policies)

1. Valuation standards and methods for securities

(1) Shares in subsidiaries and associates

Stated at cost using the moving-average method.

(2) Other securities

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

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

Shares, etc. that do not have a market price

Stated at cost using the moving-average method.

2. Valuation standards and methods of inventories

Finished goods

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

Work in process

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

Supplies

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

3. Depreciation and amortization methods for non-current assets

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

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

Major useful lives are as follows:

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

(2) Intangible assets (excluding leased assets)

Straight-line method

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

(3) Leased assets

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

4. Accounting method for deferred assets

Share issuance costs

Charged to expenses when incurred.

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

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

6. Accounting standards for reserves

Provision for retirement benefits

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

7. Significant revenue and expense accounting standards

The details of the main performance obligations in the major businesses related to revenue from contracts with the Company's customers and the timing at which the Company typically satisfies these performance obligations (when it typically recognizes revenue) are as follows:

(1) Revenue based on a license agreement

The Company earns revenues from contractual lump-sum payments, milestone revenue payments, sales of investigational drugs, and manufacturing method development contributions based on out-licensing contracts for pharmaceutical products. If a performance obligation is satisfied at a specific point in time between the conclusion and termination of a contract, revenue is recognized when the performance obligation is satisfied. If the performance obligation is not satisfied at a certain point in time, it is recorded as a contract liability and revenue is recognized over the contract period pursuant to satisfaction of the performance obligation. In addition, when variable consideration is included in a contract with a customer, only that portion of the recorded revenue that is not likely to result in a significant reduction in recorded revenues when the uncertainty regarding the amount of the variable consideration is resolved after the fact is included in the transaction price.

(2) Revenue from other sources

The Company recognizes revenue from contract manufacturing of pharmaceutical products for other research institutions. Revenue from contract manufacturing is recognized when control is transferred to the customer and the performance obligation is satisfied, which occurs when the manufactured goods are delivered to the customer and acceptance inspection is completed.

8. Capital covered by statements of cash flows

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

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

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

Restricted stock compensation plan

Based on the Company's restricted stock compensation plan, compensation paid to Directors and employees of the Company is

accounted for as expenses over the applicable period of service.

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

There is no relevant information.

(Revenue recognition)

1. Disaggregation of revenue from contracts with customers

For the fiscal year ended December 31, 2023

(Thousand yen)

Goods / Services transferred at a point in time	63,038
Goods / Services transferred over time	—
Revenue from contracts with customers	63,038
Revenue from other sources	—
Net sales to outside customers	63,038

For the fiscal year ended December 31, 2024

(Thousand yen)

Goods / Services transferred at a point in time	31,384
Goods / Services transferred over time	—
Revenue from contracts with customers	31,384
Revenue from other sources	—
Net sales to outside customers	31,384

2. Useful information in understanding revenue from contracts with customers

As presented in (Significant accounting policies) 7. Significant revenue and expense accounting standards

3. Information on satisfaction of performance obligations within contracts with customers and cash flows arising from such contracts, and the amount and timing of revenue arising from such contracts with customers' existing at the end of the current fiscal year expected to be recognized in and after the following fiscal year

(1) Contract asset and contract liability balances

The information is omitted, as there were no contract asset or contract liability balances.

(2) Transaction price allocated to the remaining performance obligations

As the Company has no significant transactions with an expected individual contract term exceeding one year, a practical simplified method is used and information on remaining performance obligations is omitted.

(Segment information, etc.)

a. Segment information

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

b. Related information

For the fiscal year ended December 31, 2023

1. Information by product and service

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

2. Information by geographical area

(1) Net sales

(Thousand yen)

Japan	U.S.	Other Asia	Total
35,000	28,038	—	63,038

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

(2) Property, plant and equipment

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

3. Information by major customer

(Thousand yen)

Name of client	Net sales	Related segment
Okayama University	35,000	Drug discovery business
Transposon Therapeutics, Inc.	28,038	Drug discovery business

For the fiscal year ended December 31, 2024

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

2. Information by geographical area
   (1) Net sales

(Thousand yen)

Japan	U.S.	Other Asia	Total
—	31,384	—	31,384

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

(2) Property, plant and equipment

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

3. Information by major customer

(Thousand yen)

Name of client	Net sales	Related segment
Transposon Therapeutics, Inc.	31,384	Drug discovery business

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

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

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

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

e. Information on gain on bargain purchase by reportable segment

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

(Per share information)

	For the fiscal year ended December 31, 2023	For the fiscal year ended December 31, 2024
Net assets per share	¥74.35	¥110.40
Loss per share	¥(108.92)	¥(77.17)

(Notes) 1. Diluted earnings per share are not presented because of the posting of loss per share, although there are residual shares.
2. The basis for the calculation of loss per share is as follows.

	For the fiscal year ended December 31, 2023	For the fiscal year ended December 31, 2024
Loss per share		
Loss (Thousand yen)	(1,938,505)	(1,684,778)
Amount not attributable to common shareholders (Thousand yen)	—	—
Loss relating to common shares (Thousand yen)	(1,938,505)	(1,684,778)
Average number of shares during the period (Shares)	17,797,360	21,831,246

(Significant subsequent events)
There is no relevant information.

5. Supplemental Information

(1) Research and Development Activities

Research and development expenses of the Company in the fiscal year under review totaled ¥1,088,997 thousand for the drug discovery business. The status of research and development activities during the fiscal year under review is as follows.

(1) Research and development structure

As of December 31, 2024, 20 persons belonged to the research and development department, accounting for 50.0% of the total number of employees.

(2) Research and development and business activities

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

1) Activities related to oncolytic virus OBP-301

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

Regarding our domestic business, in February 2024, we signed an agreement with FUJIFILM Toyama Chemical to collaborate in OBP-301 sales and established a supply chain for OBP-301 from Henogen SA, the manufacturer, to medical institutions. We are now promoting various consultations regarding a sales system after products are launched in the market. Furthermore, we have applied to the Tokyo Metropolitan Government to obtain approval for the manufacture and sale of regenerative medical products.

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

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

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

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

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

This clinical trial was conducted based on the "SAKIGAKE designation" of April 2019 at 17 clinical trial sites around Japan and a notification of completion of clinical trial was submitted to the PMDA in September 2024. The results of the clinical trial were evaluated as detailed below, in consultations with medical experts and biological statisticians. Based on these results, the Company has been negotiating with the PMDA in order to file an application for manufacturing and marketing approval of OBP-301 in Japan. The PMDA has ultimately agreed

to recognize not only the results of the clinical trials to date but also the post-marketing clinical trial implementation plan as requirements for approval, and has agreed to conduct this case under the SAKIGAKE comprehensive evaluation consultation. We will begin the SAKIGAKE comprehensive evaluation consultation in the first half of 2025. After undergoing an examination, including the post-marketing clinical trial plan, we plan to submit an application for approval in the fiscal year ending December 31, 2025.

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

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

Efficacy

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

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

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

Safety

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

i-b) **Business activities**

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

Supply chain through manufacturer, import, and shipment

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

Supply chain from FUJIFILM Toyama Chemical to medical institutions

The Company concluded a sales collaboration agreement with FUJIFILM Toyama Chemical in February 2024 to efficiently deliver OBP-301, which will have been determined to be ready for final shipment, to medical facilities in Japan. After a determination for shipment, OBP-301 will be shipped from the Company to FUJIFILM Toyama Chemical and provided to medical facilities through medical products companies designated by FUJIFILM Toyama Chemical. The Company has concluded an agreement concerning safety information with FUJIFILM Toyama Chemical in September 2024. The Company will continue to conduct various consultations such as establishing a supply chain for smooth supply of OBP-301 after products are launched in the market.

Manufacture and sale of regenerative medical products

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

In January 2024, the Company completed the designation for the three roles of marketing director, quality assurance manager, and safety management manager for manufacturing and marketing, and also established the Reliability Assurance Division. Looking forward, we will further strengthen a system that conforms with GQP and GVP. In November 2024, we applied to the Tokyo Metropolitan Government to obtain approval for the manufacture and sale of regenerative medical products, and our application is currently under review by the authority.

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

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

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

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

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

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

The Company licensed in OBP-601 from Yale University in 2006. From 2010 to 2014, it was licensed to Bristol- Myers Squibb Co. (hereinafter "BMS"), which conducted Phase IIb clinical trials as a treatment drug for HIV infection. The results demonstrated the non-inferiority of OBP-601 to existing drugs. BMS also obtained numerous clinical safety data for long-term OBP-601 toxicity studies and oncogenicity studies, but due to BMS's change of strategy, resulting in withdrawal from the HIV field, the license agreement was terminated. Results of a study by Brown University of the U.S. then suggested that nucleic acid-based reverse transcriptase inhibitors (NRTIs) of HIV suppress the aberrant expression of a retrotransposons. Subsequent research confirmed that OBP-601, which has the same effect, has high brain translocability compared to other NRTIs and strongly suppresses the production of a retrotransposon by greatly inhibiting a reverse transcriptase called LINE-1.

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

Transposon completed two double-blind Phase II clinical trials that make use of placebos. One covers progressive supranuclear palsy (PSP), while the other is on amyotrophic lateral sclerosis (ALS), with the abnormal expression of the enzyme C9 ORF, and frontotemporal degeneration (FTD). In addition, enrollment is proceeding under a single-arm Phase IIa 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. If Transposon achieves business results, including sublicense agreements for OBP-601 with third parties, it will pass on a certain percentage of revenue it obtains from the 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 and expects Transposon to achieve business results.

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

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

1) The clinical trials incorporated 42 PSP patients.
2) The trials were conducted as double-blind trials, comparing four administration groups receiving 100 mg, 200 mg, 400 mg, and placebo per day. Following 6 months of administration in these double-blind trials, the administration was switched to 400 mg of OBP-601 for all patients and follow-up was provided for an additional 6 months.
3) OBP-601 indicated tolerability for PSP patients, and 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") in cerebrospinal fluid that show the extent of damage to the cerebral nerves, continued reduction in the 400 mg administration group was indicated, but in the placebo group an increase over 24 weeks and then a reduction after switching to 400 mg administration at the start of the follow-up period were indicated.
5) IL-6, an inflammatory biomarker in cerebrospinal fluid, 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 Fast Track, which is a review system designed to facilitate new-drug approval and review, in May 2024.

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

Administration under the clinical trial for C9-ALS/FTD began in January 2022, and target enrollment was concluded in March 2023. We have also completed a long-term follow-up study on the enrolled patients. 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. Additionally, in January 2025, an End of Phase 2 meeting regarding ALS was held with the FDA. 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.
2) The assessment using a 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 in the 24 weeks from the start of administration.
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.
5) Transposon plans to move forward with Phase III clinical trials on OBP-601 for C9-ALS.

iii) **Phase IIa clinical trial for AGS**

In July 2023, Transposon started administration under a Phase IIa 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.

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 conducting non-clinical trials on OBP-702, which was adopted as a grant program by the Japan Agency for Medical Research and Development (AMED). In particular, an experiment on gemcitabine-resistant pancreatic cancer cell lines using mouse models, OBP-702, used in combination with PD-L1 antibodies, exhibited stronger anti-tumor effects 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. Development of OBP-702 will continue within the scope of the grant in order to concentrate management resources on OBP-301 to submit for approval.

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, maintaining a framework that can respond to new pandemics.

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 (NDA preparation)
		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 (C9-ALS) / frontotemporal degeneration (FTD)	Monotherapy (double-blind trial)	U.S. and Europe	Phase II (Phase III preparation)
	Aicardi-Goutières Syndrome (AGS)	Monotherapy	Europe	Phase IIa
	Alzheimer's disease.	TBD	U.S.	Phase II preparation
OBP-702	Solid tumor	Anti-PD-(L)1 antibody (expected)	Japan	Pre-clinical
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