NB: this is a summary translation of the press release original drafted in Japanese for the disclosure required in compliance with the TSE regulations.

Non-consolidated Financial Results for the Fiscal Year Ended December 31, 2023 [Japanese GAAP]

February 9, 2024

Company name: Oncolys BioPharma Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4588
URL: http://www.oncolys.com
Representative: Yasuo Urata, President & CEO
Contact: Keiji Yoshimura, Vice President
Email: oncolys_information@oncolys.com
Scheduled date of Annual General Meeting of Shareholders: March 28, 2024
Scheduled date of commencing dividend payments: —
Scheduled date of filing annual securities report: March 29, 2024
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, 2023 (January 1, 2023 to December 31, 2023)

(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, 2023	63	(93.5)	(1,929)	-	(1,913)	-	(1,938)	-
December 31, 2022	976	51.9	(1,204)	-	(1,163)	-	(1,148)	-

	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, 2023	(108.92)	-	(107.4)	(81.6)	-
December 31, 2022	(66.31)	-	(40.0)	(33.5)	-

(Reference) Equity in earnings of affiliates: Fiscal year ended December 31, 2023: ¥- million
Fiscal year ended December 31, 2022: ¥- million

(2) Financial Position

	Total assets	Net assets	Equity ratio	Net assets per share
	Million yen	Million yen	%	Yen
As of December 31, 2023	2,040	1,474	71.5	74.35
As of December 31, 2022	2,650	2,159	81.2	124.20

(Reference) Equity: As of December 31, 2023: ¥1,459 million
As of December 31, 2022: ¥2,151 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, 2023	(1,336)	(5)	1,142	1,287
December 31, 2022	(1,717)	20	(113)	1,466

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, 2022	-	0.00	-	0.00	0.00	-	-	-
Fiscal year ended December 31, 2023	-	0.00	-	0.00	0.00	-	-	-
Fiscal year ending December 31, 2024 (Forecast)	-	0.00	-	0.00	0.00		-	

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

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: Yes
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, 2023: 19,717,100 shares
December 31, 2022: 17,405,200 shares

2) Total number of treasury shares at the end of the period:
December 31, 2023: 88,738 shares
December 31, 2022: 82,238 shares

3) Average number of shares during the period:
Fiscal year ended December 31, 2023: 17,797,360 shares
Fiscal year ended December 31, 2022: 17,327,407 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, 2023 showed favorable results, with the Diffusion Index (hereinafter "DI") of business conditions for large companies in the Bank of Japan's Tankan survey for December 2023 exceeding market expectations for both manufacturing and non-manufacturing companies, and DI business conditions rose across a wide range of industries. On the other hand, with the conflict in Israel and the rapid depreciation of the yen due to the raised policy interest rates in the U.S. and Europe, the volatile situation in both Japan and overseas seems likely to continue.

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 Telomelysin (OBP-301) virotherapy for cancer. In addition, concerning LINE-1 inhibitor OBP-601 (censavudine), Transposon Therapeutics, Inc. (hereinafter "Transposon") is conducting clinical trials at its own 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, 2023, net sales were ¥63,038 thousand (net sales of ¥976,182 thousand in the previous fiscal year), and operating loss was ¥1,929,986 thousand (operating loss of ¥1,204,506 thousand in the previous fiscal year). In addition, the Company recorded interest income of ¥1,475 thousand, foreign exchange gains of ¥27,598 thousand, and other items as non-operating income, and interest expenses of ¥3,602 thousand, share issuance costs of ¥8,777 thousand, and other items as non-operating expenses. Ordinary loss was ¥1,913,816 thousand (ordinary loss of ¥1,163,008 thousand in the previous fiscal year). The Company also recorded gain on sale of non-current assets of ¥136 thousand as extraordinary income and an impairment loss of ¥21,898 thousand on the analytical equipment related to Telomelysin owned by the Company, as an extraordinary loss. As a result, net loss was ¥1,938,505 thousand (net loss of ¥1,148,938 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 ¥2,040,598 thousand (23.0% decrease compared with the end of the previous fiscal year), owing partly to a decrease in cash and deposits. Liabilities were ¥566,500 thousand (15.2% increase compared with the end of the previous fiscal year), owing partly to an increase in accounts payable - other and long-term loans payable. Net assets were ¥1,474,097 thousand (31.7% decrease 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 ¥1,287,763 thousand (12.2% decrease 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 ¥1,336,922 thousand (a cash outflow of ¥1,717,135 thousand in the previous fiscal year). This is primarily attributable to loss before income taxes of ¥1,935,578 thousand and impairment losses of ¥21,898 thousand, a decrease in advance payments - other of ¥223,713 thousand, a decrease

in accounts receivable - other of ¥123,411 thousand, and an increase in accounts payable - other of ¥132,727 thousand.

(Cash flows from investing activities)

Net cash flows used in investing activities were ¥5,392 thousand (a cash inflow of ¥20,117 thousand in the previous fiscal year). This is primarily attributable to purchase of property, plant and equipment of ¥5,686 thousand.

(Cash flows from financing activities)

Net cash flows provided by financing activities were ¥1,142,542 thousand (a cash outflow of ¥113,830 thousand in the previous fiscal year). This is primarily attributable to proceeds from issuance of common shares of ¥1,223,450 thousand, proceeds from long-term loans payable of ¥100,000 thousand, repayments of long-term loans payable of ¥194,444 thousand and repayments of lease obligations of ¥4,540 thousand.

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

	Fiscal year ended December 31, 2021	Fiscal year ended December 31, 2022	Fiscal year ended December 31, 2023
Equity ratio (%)	83.6	81.2	71.5
Equity ratio based on fair value (%)	213.3	344.4	545.4
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 domestic distribution partnership agreement for Telomelysin, achieving the development event of LINE-1 inhibitor OBP-601, for which we have a license agreement with Transposen, and that company's IPO, or 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 take 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 Telomelysin and the next-generation Telomelysin 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 (censavudine), 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 Telomelysin 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 license agreements and marketing partners. Therefore, the Company considers that its research and development expenses necessary to obtain Proof of Concept (POC) in the initial 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 a fabless management model utilizing outsourcing in order to realize efficient progress from pre-clinical to clinical trials, with focus placed on hiring and cultivating personnel specializing in project management of drug discovery research and development. By maximizing the value of our pipeline by achieving rapid progression to the next stage in development, the Company is able to conclude licensing agreements and marketing agreements with major pharmaceutical companies and biotech companies on better conditions.

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 and generates royalty revenues after products are launched in the market, and a pharmaceutical company-type business model in which the Company earns revenues by obtaining its own manufacturing and sales approval and supplying commercial drug formulations to its 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 covers the whole process from the search and invention of prospective pharmaceuticals and detection drugs to pre-clinical trials and initial clinical trials (i.e., proof of concept), and the main role of the Company is to act as a bridge between the pre-clinical and clinical stages (i.e., translational research). 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. 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 "OUS"). 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 CMOs (Contract 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, 2022	As of December 31, 2023
Assets		
Current assets		
Cash and deposits	1,711,280	1,532,844
Finished goods	8,434	–
Work in process	12,666	–
Supplies	3,149	5,342
Advance payments – other	506,316	282,602
Prepaid expenses	47,970	33,338
Short-term loans receivable from subsidiaries and associates	39,813	–
Accounts receivable – other	174,310	51,781
Income taxes refund receivable	28,299	–
Consumption taxes receivable	75,982	49,964
Advances paid	29	–
Other	501	9
Total current assets	2,608,754	1,955,883
Non-current assets		
Property, plant and equipment		
Buildings	2,794	3,128
Accumulated depreciation	(2,794)	(3,128)
Buildings, net	–	–
Machinery and equipment	–	924
Accumulated depreciation	–	(924)
Machinery and equipment, net	–	–
Tools, furniture and fixtures	65,939	66,967
Accumulated depreciation	(65,939)	(66,967)
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
Lease and guarantee deposits	21,149	20,990
Long-term prepaid expenses	–	135
Other	19	4
Total investments and other assets	42,204	84,714
Total non-current assets	42,204	84,714
Total assets	2,650,959	2,040,598

(Thousand yen)

	As of December 31, 2022	As of December 31, 2023
Liabilities		
Current liabilities		
Short-term loans payable	227,776	127,776
Lease obligations	3,581	7,565
Accounts payable – other	60,858	193,354
Accrued expenses	17,099	19,119
Income taxes payable	2,931	18,844
Deposits received	9,392	11,870
Total current liabilities	321,639	378,531
Non-current liabilities		
Long-term loans payable	155,544	161,100
Lease obligations	6,758	18,729
Provision for retirement benefits	7,748	8,140
Total non-current liabilities	170,051	187,969
Total liabilities	491,690	566,500
Net assets		
Shareholders' equity		
Capital stock	3,000,000	3,623,165
Capital surplus		
Legal capital surplus	586,425	1,209,590
Total capital surpluses	586,425	1,209,590
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(1,434,694)	(3,373,199)
Total retained earnings	(1,434,694)	(3,373,199)
Treasury shares	(142)	(142)
Total shareholders' equity	2,151,589	1,459,413
Share acquisition rights	7,680	14,683
Total net assets	2,159,269	1,474,097
Total liabilities and net assets	2,650,959	2,040,598

(2) Statements of Income

(Thousand yen)

	For the fiscal year ended December 31, 2022	For the fiscal year ended December 31, 2023
Net sales	976,182	63,038
Cost of sales		
Cost of service	637,695	32,433
Beginning finished goods	8,434	8,434
Total	8,434	8,434
Finished goods transfer to other account	–	8,434
Ending finished goods	8,434	–
Gross profit	338,487	30,604
Selling, general and administrative expenses	1,542,993	1,960,591
Operating loss	(1,204,506)	(1,929,986)
Non-operating income		
Interest income	587	1,475
Dividend income	3	3
Subsidy income	–	2,953
Foreign exchange gains	62,639	27,598
Other	37	177
Total non-operating income	63,267	32,208
Non-operating expenses		
Interest expenses	3,945	3,602
Amortization of restricted stock remuneration	17,793	629
Share acquisition rights issuance costs	–	3,029
Share issuance costs	30	8,777
Other	0	–
Total non-operating expenses	21,769	16,038
Ordinary loss	(1,163,008)	(1,913,816)
Extraordinary income		
Gain on sale of bonds	21,406	–
Gain on sale of non-current assets	–	136
Total extraordinary income	21,406	136
Extraordinary losses		
Impairment loss	4,403	21,898
Total extraordinary losses	4,403	21,898
Loss before income taxes	(1,146,005)	(1,935,578)
Income taxes – current	2,932	2,926
Total income taxes	2,932	2,926
Loss	(1,148,938)	(1,938,505)

(3) Statements of Changes in Equity

For the fiscal year ended December 31, 2022

(Thousand yen)

	Shareholders' equity							
	Capital stock	Capital surplus			Retained earnings		Treasury shares	Total shareholders' equity
		Legal capital surplus	Other capital surplus	Total capital surpluses	Other retained earnings Retained earnings brought forward	Total retained earnings		
Balance at beginning of current period	9,039,516	9,031,904	31,740	9,063,645	(14,516,735)	(14,516,735)	(113)	3,586,312
Cumulative effects of changes in accounting policies					(285,756)	(285,756)		(285,756)
Restated balance	9,039,516	9,031,904	31,740	9,063,645	(14,802,491)	(14,802,491)	(113)	3,300,556
Changes of items during period								
Capital reduction	(6,039,516)	(8,445,478)	14,484,995	6,039,516				–
Deficit disposition			(14,516,735)	(14,516,735)	14,516,735	14,516,735		–
Loss					(1,148,938)	(1,148,938)		(1,148,938)
Purchase of treasury shares							(28)	(28)
Total changes of items during period	(6,039,516)	(8,445,478)	(31,740)	(8,477,219)	13,367,797	13,367,797	(28)	(1,148,966)
Balance at end of current period	3,000,000	586,425	–	586,425	(1,434,694)	(1,434,694)	(142)	2,151,589

	Share acquisition rights	Total net assets
Balance at beginning of current period	7,680	3,593,992
Cumulative effects of changes in accounting policies		(285,756)
Restated balance	7,680	3,308,236
Changes of items during period		
Capital reduction		–
Deficit disposition		–
Loss		(1,148,938)
Purchase of treasury shares		(28)
Total changes of items during period	–	(1,148,966)
Balance at end of current period	7,680	2,159,269

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

(4) Statements of Cash Flows

(Thousand yen)

	For the fiscal year ended December 31, 2022	For the fiscal year ended December 31, 2023
Cash flows from operating activities		
Loss before income taxes	(1,146,005)	(1,935,578)
Depreciation	914	2,286
Impairment loss	4,403	21,898
Amortization of restricted stock remuneration	17,793	629
Gain on sale of bonds	(21,406)	–
Share-based remuneration expenses	58,134	9,433
Increase (decrease) in provision for retirement benefits	1,992	391
Interest and dividend income	(590)	(1,478)
Interest expenses	3,945	3,602
Share acquisition rights issuance costs	–	3,029
Share issuance costs	30	8,777
Foreign exchange losses (gains)	(72,723)	(24,090)
Decrease (increase) in notes and accounts receivable – trade	352,148	–
Decrease (increase) in inventories	(12,593)	18,907
Decrease (increase) in prepaid expenses	14,168	4,437
Decrease (increase) in accounts receivable – other	(198,392)	123,411
Decrease (increase) in consumption taxes refund receivable	(55,677)	28,015
Decrease (increase) in advance payments – other	(272,301)	223,713
Increase (decrease) in accounts payable – other	(45,371)	132,727
Increase (decrease) in contract liabilities	(285,756)	–
Other, net	(54,970)	20,812
Subtotal	(1,712,259)	(1,359,074)
Interest and dividend income received	553	616
Interest expenses paid	(3,962)	(3,836)
Income taxes refund (paid)	(1,466)	25,372
Net cash provided by (used in) operating activities	(1,717,135)	(1,336,922)
Cash flows from investing activities		
Payments into time deposits	(1)	(1)
Proceeds from sale of bonds	21,406	–
Purchase of property, plant and equipment	(1,358)	(5,686)
Proceeds from sale of property, plant and equipment	–	136
Proceeds from refund of lease and guarantee deposits	71	159
Net cash provided by (used in) investing activities	20,117	(5,392)
Cash flows from financing activities		
Net increase (decrease) in short-term loans payable	(100,000)	–
Proceeds from long-term loans payable	100,000	100,000
Repayments of long-term loans payable	(111,104)	(194,444)
Repayments of lease obligations	(2,667)	(4,540)
Proceeds from issuance of common shares	–	1,223,450
Proceeds from issuance of share acquisition rights	–	18,076
Purchase of treasury shares	(28)	–
Other payments	(30)	–
Net cash provided by (used in) financing activities	(113,830)	1,142,542
Effect of exchange rate change on cash and cash equivalents	67,413	21,334
Net increase (decrease) in cash and cash equivalents	(1,743,434)	(178,437)
Cash and cash equivalents at beginning of year	3,209,635	1,466,201
Cash and cash equivalents at end of period	1,466,201	1,287,763

(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

(1) Allowance for doubtful accounts

To prepare for potential credit losses on receivables, an estimated uncollectible amount is recorded at the amount calculated based on the historical rate of credit loss with respect to normal receivables, and based on the recoverability of individual cases for specified receivables such as doubtful receivables that may not be recoverable.

(2) 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.

(Changes in accounting policies)

(Application of Implementation Guidance on Accounting Standard for Fair Value Measurement)

The Company has applied the "Implementation Guidance on Accounting Standard for Fair Value Measurement" (ASBJ Guidance No. 31, June 17, 2021; hereinafter "Fair Value Measurement Guidance") from the beginning of the period, and will prospectively apply the new accounting policies stipulated by the Fair Value Measurement Guidance in accordance with the transitional treatment provided in Paragraph 27-2 of the Fair Value Measurement Guidance. This does not affect the financial statements.

(Changes in presentation method)

(Statements of Cash Flows)

"Share issuance costs" included in "Other" in "Cash flows from operating activities" in the previous fiscal year have, from the current fiscal year, increased in importance in terms of monetary amount, and the Company has therefore decided to present it as a separate item.

As a result, (54,940) thousand yen presented as "Other" in "Cash flows from operating activities" in the previous fiscal year has been reclassified as "Share issuance costs" of 30 thousand yen and "Other" of (54,970) thousand yen.

(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, 2022

(Thousand yen)

Goods / Services transferred at a point in time	63,075
Goods / Services transferred over time	913,107
Revenue from contracts with customers	976,182
Revenue from other sources	—
Net sales to outside customers	976,182

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

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, 2022

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
950,394	25,788	—	976,182

(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
Chugai Pharmaceutical Co., Ltd.	913,107	Drug discovery business
Okayama University	37,287	Drug discovery business
Transposon Therapeutics, Inc.	25,788	Drug discovery business

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

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, 2022	For the fiscal year ended December 31, 2023
Net assets per share	¥124.20	¥74.35
Loss per share	¥(66.31)	¥(108.92)

(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, 2022	For the fiscal year ended December 31, 2023
Loss per share		
Loss (Thousand yen)	(1,148,938)	(1,938,505)
Amount not attributable to common shareholders (Thousand yen)	—	—
Loss relating to common shares (Thousand yen)	(1,148,938)	(1,938,505)
Average number of shares during the period (shares)	17,327,407	17,797,360

(Significant subsequent events)

Capital increase through exercise of share acquisition rights

During the period from January 1 to January 31, 2024, a portion of the 19th series share acquisition rights (with exercise price adjustment clause) was exercised as follows.

(1) Number of share acquisition rights exercised	947 units
(2) Class and number of shares issued	94,700 shares of common stock
(3) Total amount exercised	49,160 thousand yen
(4) Amount of increase in capital stock	24,869 thousand yen
(5) Amount of increase in legal capital surplus	24,869 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 288 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 January 31, 2024 was 19,811,800 shares, capital stock was 3,648,034 thousand yen, and legal capital surplus was 1,234,459 thousand yen.

5. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the fiscal year under review totaled ¥1,351,940 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, 2023, 19 persons belonged to research and development department, accounting for 47.5% 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 Telomelysin (OBP-301) (International Nonproprietary Name: suratadenoturev) virotherapy for cancer

The Company is conducting a "Phase II clinical trial in combination with radiation therapy for esophageal cancer" for Telomelysin, for which the Ministry of Health, Labour and Welfare has granted "SAKIGAKE designation" for regenerative medicine products in Japan, and disclosed top-line data through a technical committee meeting in October 2023. Based on the results, we plan to conduct negotiations with PMDA with a view toward applying for new drug approval for Telomelysin in Japan in 2024. In terms of supply for Telomelysin, we have been making progress on commercial scale viral production development, and in November 2023 commenced manufacturing for process validation, with plans for commercial manufacturing in 2024. In addition, in December 2023, the Company entered into an agreement with MITSUI-SOKO HOLDINGS Co., Ltd. (hereinafter "MITSUI-SOKO HD"), for a domestic Telomelysin manufacturing facility. Furthermore, we have been working to establish our own manufacturing and sales system for Telomelysin, and in February 2024 signed an agreement with FUJIFILM Toyama Chemical Co., Ltd. (hereinafter "FUJIFILM Toyama Chemical") to collaborate with Telomelysin sales. As a result, we have established a value chain in which Telomelysin is formulated by Belgium-based Henogen SA, imported into Japan, processed into final packaging at the domestic manufacturing facility of MITSUI-SOKO HD, and delivered to medical facilities by FUJIFILM Toyama Chemical.

Meanwhile, in overseas, in December 2023, the Company signed an agreement with Cornell University, which in turn signed an agreement with Merck & Co., Inc. (hereinafter "Merck") to establish a joint development system for Telomelysin and the immune checkpoint inhibitor pembrolizumab for the treatment of gastric cancer in the U.S. This is a Phase II investigator-initiated clinical trial, under which administration is planned to begin in 2024, with the Company and Merck equally sharing research and development expenses.

Currently, Telomelysin is undergoing the following four clinical trials in Japan and overseas, including the clinical trial for which enrollment has been completed:

i) Phase II clinical trial in combination with radiation therapy for esophageal cancer;
ii) Phase II investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for gastric cancer/gastroesophageal junction cancer;
iii) Phase II investigator-initiated clinical trial of second-line treatment in combination with immune checkpoint inhibitors for gastric cancer/gastroesophageal junction cancer; and
iv) Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer

Regarding the above i) "Phase II clinical trial in combination with radiation therapy for esophageal cancer," trials are ongoing based on the "SAKIGAKE designation" of April 2019 at 17 clinical trial sites around Japan, and we disclosed top-line data in October 2023. The principal results of the top-line data are as follows.

1. 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-CR ([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."

1. Safety

The main side-effects related to Telomelysin 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.

We have obtained the agreement of medical experts and biological statisticians on the interpretation of the result of this clinical trial.

Based on the results of the above-mentioned top-line data, the Company is currently in consultations with PMDA regarding non-clinical trials, clinical trials, manufacturing, etc., to submit a new drug application of Telomelysin in Japan in 2024.

With regard to Telomelysin's supply chain, the Company is currently moving forward on manufacturing development for commercial production at Belgium's Henogen SA with a view to submitting a new drug application for Telomelysin. We began process validation in November 2023 and plan to start commercial manufacturing in 2024, when the new drug application will be submitted. In addition, in December 2023, we concluded an agreement with MITSUI-SOKO HD which will serve as a domestic manufacturing base responsible for final packaging and storage, etc. of Telomelysin formulations, as they possess extensive experience in the logistics field related to advanced medicine, including handling of regenerative medical products, as well as knowledge and experience in ensuring quality in regenerative medical products. In June 2023, we signed a contract with Eurofins Analytical Science Laboratories (Kyoto City), and together with our Kobe Research Lab, we are starting to conduct validation quality tests necessary to make a final determination for shipment of Telomelysin. Furthermore, to efficiently deliver Telomelysin, which has been determined to be ready for final shipment, to medical facilities in Japan, we concluded a sales collaboration agreement with FUJIFILM Toyama Chemical in February 2024.

Through these agreements, the Company will work to establish a distribution system capable of providing a stable, high-quality supply of Telomelysin along the entire supply chain, from overseas to medical institutions in Japan.

The Company will be positioned as a manufacturer and distributor shipping Telomelysin to Japan, regardless of whether we have a sales collaboration agreement with FUJIFILM Toyama Chemical. In addition to the regulatory review of the quality, efficacy, and safety of Telomelysin itself, its manufacturing and marketing is subject to review by the Tokyo Metropolitan Government for conformity to "GQP (Good Quality Practice)," and "GVP (Good Vigilance Practice)" and other requirements, and there is the necessity to obtain approval for manufacture and sale of regenerative medical products.

In January 2024, the Company completed hiring 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, upon further developing a system that conforms with GQP and GVP, we intend to apply to the Tokyo Metropolitan Government for a license to manufacture and market regenerative medicine products by the time we apply for approval of Telomelysin, as we have the capacity to assume ultimate responsibility for quality assurance and safety control operations for the shipment of Telomelysin to the market.

Regarding the above ii) "Phase II investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for gastric cancer/gastroesophageal junction cancer," administration began in May 2019 led by Cornell University in the U.S. with the goal of evaluating the efficacy and safety of Telomelysin and pembrolizumab, and was performed for the most advanced patients who have been treated in the past. Long-term survival has been confirmed in 3 of the 16 patients enrolled so far, and this result was deemed to satisfy the standard set for efficacy in the trial. The interim analysis results of this clinical trial were presented by Dr. Manish A. Shah of Cornell University in the U. S. at annual meetings of the American Society of Clinical Oncology in June 2023 (ASCO 2023) and the Society for Immunotherapy of Cancer in November 2023 (SITC 2023).

Regarding the above iii) "Phase II investigator-initiated clinical trial of second-line treatment in combination with immune checkpoint inhibitor pembrolizumab 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 Merck 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 Merck, which established a joint development system. The Company will provide Telomelysin, and Merck will provide the immune checkpoint inhibitor pembrolizumab to Cornell University. In addition, the expenses for the clinical trial will be shared equally between the Company and Merck. Administration under the clinical trial will begin in 2024.

Regarding the above iv) "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 Telomelysin in combination with chemoradiotherapy. This clinical trial is being conducted in six facilities within the U.S., and the enrollment of all six patients for the first stage has been completed, while in the second stage administration is being provided to four patients. Thus far, there have been no reports of problematic side-effects. Telomelysin 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 for seven years after the approval of Telomelysin 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 higher 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 is currently conducting two double-blind Phase IIa clinical trials that make use of placebos at numerous facilities, both in Europe and the U.S. 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, in July 2023, administration began under a single-arm Phase IIa clinical trial in Europe for the treatment of Aicardi-Goutières Syndrome (AGS).

Administration to the first patient under the Phase IIa clinical trial for PSP began in November 2021, and enrollment of the target number of patients was concluded in August 2022. We have received a report from Transposon on the results of the interim analysis, and the main details of the analysis are as follows.

1) It suggested that OBP-601 lowers neurofilament light chains (hereinafter "NfL") in the cerebrospinal fluid of patients with PSP.
2) It suggested that OBP-601 reduces IL-6, a biomarker of neuroinflammation, in cerebrospinal fluid.
3) To date, there have been no reports of safety problems that necessitate the termination of the trials.

Having received the above report from Transposon, the Company has made the following observations.

1) Rather than within blood, OBP-601 lowered the NfL count in "cerebrospinal fluid." This result suggests that OBP-601 directly reduced nerve damage in the central nervous system.
2) OBP-601 reduced IL-6, a biomarker of neuroinflammation, in cerebrospinal fluid. This result suggests that OBP-601 suppresses inflammation in nerve tissue by inhibiting LINE-1.
3) Changes in these biomarkers in cerebrospinal fluid suggest that OBP-601 migrates into the brain and also exerts its effects in a clinical setting.

These results will be presented at AD/PD™ 2024 (International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders) in March 2024.

In addition, administration under the clinical trial for C9-ALS and FTD began in January 2022, and target enrollment was concluded in March 2023. We are now conducting 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.

Furthermore, in July 2023, Transposon started administration under a new 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.

These clinical trials on OBP-601 are proceeding entirely at Transposon's expense based on the license agreement. 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.

3) Activities related to next generation Telomelysin (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 Telomelysin. 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 Telomelysin, which we aim to submit for approval in 2024.

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 Telomelysin, for which we aim to apply for approval in 2024. 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

Regarding TelomeScan, the Company set up a "Collaborative Research Program on Minimally Invasive Cancer Detection Method Using TelomeScan," in June 2021, with Juntendo University, aimed at establishing a platform for automated detection of live Circulating Tumor Cells (CTC) within the blood of cancer patients. However, the development with Juntendo University has been delayed due to the time required to acquire images compared to initial plans, given the large number of images that need to be acquired for AI image learning. We have lowered the priority of these activities in order to concentrate management resources on Telomelysin, which we aim to submit for approval in 2024.

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. OBP-801 received a patent as a cancer treatment and prevention drug in combination with molecular targeting drug in Japan in September 2023.

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) held in April 2023. Going forward, there is hope for development in the form of eye drops. We have lowered the priority of these activities in order to concentrate management resources on Telomelysin, which we aim to submit for approval in 2024.

The development status of pipeline products is as follows.

Product	Indication	Combination therapy	Development region	Development stage
Telomelysin (OBP-301) (suratadenoturev)	Esophageal cancer	Radiation therapy	Japan	Phase II (NDA preparation)
		Chemoradiotherapy	U.S.	Phase I
		Anti-PD-1 antibody pembrolizumab	Japan	Phase I (Enrollment complete)
	Gastric/ gastroesophageal junction cancer	Anti-PD-1 antibody pembrolizumab	U.S.	Phase II (Enrollment complete)
		Immune checkpoint inhibitor pembrolizumab	U.S.	Phase II
	Hepatocellular cancer (HCC)	Monotherapy	South Korea and Taiwan	Phase I (complete)
OBP-601 (censavudine)	Progressive supranuclear palsy (PSP)	Monotherapy	U.S.	Phase IIa (Enrollment complete)
	Amyotrophic lateral sclerosis (C9-ALS) / frontotemporal degeneration (FTD)	Monotherapy	U.S. and Europe	Phase IIa (Enrollment complete)
	Aicardi-Goutières Syndrome (AGS)	Monotherapy	Europe	Phase IIa
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