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 Nine Months Ended September 30, 2023 [Japanese GAAP]

November 10, 2023

Company name: Oncolys BioPharma Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4588
URL: https://www.oncolys.com
Representative: Yasuo Urata, President & CEO
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Scheduled date of filing quarterly securities report: November 10, 2023
Scheduled date of commencing dividend payments: —
Availability of supplementary briefing material on quarterly financial results: No
Schedule of quarterly financial results briefing session: No

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

1. Financial Results for the Nine Months Ended September 30, 2023 (January 1, 2023 to September 30, 2023)

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

	Net sales		Operating profit		Ordinary profit		Profit	
Nine months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
September 30, 2023	63	(92.0)	(1,311)	–	(1,270)	–	(1,272)	–
September 30, 2022	784	–	(937)	–	(854)	–	(835)	–

(Note) The Company has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020), etc. from the beginning of the three months ended March 31, 2022. As the application of the accounting standard, etc. has a significant effect on net sales, the Company does not present the percentage of change in net sales for the nine months ended September 30, 2022 from the previous corresponding period.

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2023	(73.15)	–
September 30, 2022	(48.20)	–

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of September 30, 2023	1,775	1,321	73.1
As of December 31, 2022	2,650	2,159	81.2

(Reference) Equity: As of September 30, 2023: ¥1,297 million
As of December 31, 2022: ¥2,151 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended December 31, 2022	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2023	–	0.00	–		
Fiscal year ending December 31, 2023 (Forecast)				0.00	0.00

(Note) Revision to the forecast for dividends announced most recently: No

3. Financial Results Forecast for the Fiscal Year Ending December 31, 2023 (January 1, 2023 to December 31, 2023)

Financial results forecast is not disclosed due to the difficulty of making reasonable estimates. For details, please see "1. Qualitative Information on Quarterly Financial Results for the Period under Review (3) Explanation of Financial Results Forecast and Other Forward-looking Information on page 2 of the supplementary material.

*** Notes:**

(1) Accounting policies adopted specially for the preparation of quarterly financial statements: No

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

(3) Total number of issued shares (common shares)
1) Total number of issued shares at the end of the period (including treasury shares):
September 30, 2023: 18,175,300 shares
December 31, 2022: 17,405,200 shares

2) Total number of treasury shares at the end of the period:
September 30, 2023: 88,738 shares
December 31, 2022: 82,238 shares

3) Average number of shares during the period:
Nine months ended September 30, 2023: 17,399,785 shares
Nine months ended September 30, 2022: 17,328,525 shares

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

* Explanation of the proper use of financial results forecast and other notes

(Note regarding forward-looking statements, etc.)

The earnings forecasts and other forward-looking statements herein are based on information available to the Company at the time of the release of these materials and certain assumptions deemed reasonable, and do not represent a commitment from the Company that they will be achieved. In addition, actual financial results, etc. may differ significantly due to a wide range of factors. For the assumptions used in forecasting financial results and notes regarding the use of financial forecasts, etc., please see "1. Qualitative Information on Quarterly Financial Results for the Period under Review (3) Explanation of Financial Results Forecast and Other Forward-looking Information" on page 2 of the supplementary material.

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

(1) Explanation of Business Results

During the nine months ended September 30, 2023, the Japanese economy saw improvement against the background of production recovery due to relaxation of supply constraints and increase in foreign visitors to Japan, as the Bank of Japan's Tankan survey for September released in October reported improvement in business confidence among manufacturing and non-manufacturing large companies. Meanwhile, the global economy continued to grow slowly and moderately while economic recovery was delayed, as the U.S. Federal Open Market Committee (FOMC) decided to keep interest rates unchanged in September, and the European Central Bank (ECB) raised interest rates for 10th consecutive time and implied the ending of rate hikes in September.

Under these circumstances, the Company has been pursuing a vision of "Providing new options for future cancer treatments, and leaving our footprint in the history of cancer treatment," thus striving to increase managerial efficiency and actively expand research, development, and licensing activities.

In particular, the Company is promoting research, development, and business activities with a business concept of "virus drug discovery" within the business fields of "virotherapy for cancer" and "drugs for the treatment of serious viral infectious diseases," with a focus on Telomelysin (OBP-301), a virotherapy for cancer, and OBP-2011 for the treatment of viral infectious diseases. In addition, concerning OBP-601 (censavudine), a nucleoside reverse transcriptase inhibitor, Transposon Therapeutics, Inc. (hereinafter "Transposon") is conducting multiple clinical trials in Europe and the U.S. entirely at its own expense based on a license agreement.

For details of the Company's activities, please refer to "3. Supplemental Information (1) Research and development activities."

For the nine months ended September 30, 2023, net sales were ¥63,038 thousand (net sales of ¥784,509 thousand in the same period of the previous fiscal year), and operating loss was ¥1,311,038 thousand (operating loss of ¥937,381 thousand in the same period of the previous fiscal year). In addition, the Company recorded interest income of ¥1,007 thousand, foreign exchange gains of ¥47,674 thousand, and subsidy income for IT introduction support business of ¥2,953 thousand as non-operating income, and interest expenses of ¥2,779 thousand, amortization of restricted stock remuneration of ¥629 thousand, and share issuance costs of ¥8,155 thousand as non-operating expenses, resulting in ordinary loss of ¥1,270,785 thousand (ordinary loss of ¥854,455 thousand in the same period of the previous fiscal year). The Company also recorded gain on sale of non-current assets of ¥136 thousand as extraordinary income. As a result, net loss was ¥1,272,843 thousand (net loss of ¥835,248 thousand in the same period of the previous fiscal year).

(2) Explanation of Financial Position

Assets at the end of the third quarter of the fiscal year under review were ¥1,775,899 thousand (33.0% decrease compared with the end of the previous fiscal year), primarily due to a decrease in cash and deposits. Liabilities were ¥454,140 thousand (7.6% decrease compared with the end of the previous fiscal year), mainly on account of an increase in accounts payable - other and contract liabilities. Net assets were ¥1,321,759 thousand (38.8% decrease compared with the end of the previous fiscal year), due to net loss incurred, as well as other factors.

(3) Explanation of Financial Results Forecast and Other Forward-looking Information

The Company still has a small stable revenue base, and our financial results fluctuate greatly depending on contractual lump-sum payments from the conclusion of new contracts and milestone revenue payments generated from licensees achieving events. There is also a risk that disclosing our full-year earnings forecast for the fiscal year ending December 31, 2023 could affect our negotiations on economic terms for the Telomelysin domestic distribution partnership agreement planned for 2023, as well as our negotiations on terms for the establishment of a collaborative research system for Telomelysin with a major pharmaceutical company in the United States that markets an immune checkpoint inhibitor.

For these reasons, we believe that it is difficult to calculate an appropriate and reasonable figure for the earnings forecast at this time due to the many undetermined factors that will affect our business performance, and therefore, we refrain from disclosing the forecast.

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousand yen)

	As of December 31, 2022	As of September 30, 2023
Assets		
Current assets		
Cash and deposits	1,711,280	1,208,152
Finished goods	8,434	6,124
Work in process	12,666	–
Supplies	3,149	4,835
Advance payments – other	506,316	315,817
Prepaid expenses	47,970	33,167
Short-term loans receivable from subsidiaries and associates	39,813	–
Accounts receivable – other	174,310	83,467
Income taxes refund receivable	28,299	–
Consumption taxes receivable	75,982	32,257
Advances paid	29	–
Other	501	50
Total current assets	2,608,754	1,683,872
Non-current assets		
Property, plant and equipment		
Buildings	2,794	4,794
Accumulated depreciation	(2,794)	(2,961)
Buildings, net	–	1,833
Tools, furniture and fixtures	65,939	69,201
Accumulated depreciation	(65,939)	(66,453)
Tools, furniture and fixtures, net	–	2,748
Total property, plant and equipment	–	4,581
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	–	44,874
Lease and guarantee deposits	21,149	20,990
Long-term prepaid expenses	–	541
Other	19	4
Total investments and other assets	42,204	87,445
Total non-current assets	42,204	92,027
Total assets	2,650,959	1,775,899

(Thousand yen)

	As of December 31, 2022	As of September 30, 2023
Liabilities		
Current liabilities		
Short-term loans payable	227,776	141,666
Lease obligations	3,581	3,642
Accounts payable – other	60,858	84,559
Accrued expenses	17,099	18,356
Income taxes payable	2,931	8,545
Deposits received	9,392	13,276
Total current liabilities	321,639	270,046
Non-current liabilities		
Long-term loans payable	155,544	172,212
Lease obligations	6,758	4,018
Provision for retirement benefits	7,748	7,863
Total non-current liabilities	170,051	184,093
Total liabilities	491,690	454,140
Net assets		
Shareholders' equity		
Capital stock	3,000,000	3,209,462
Capital surplus		
Legal capital surplus	586,425	795,887
Total capital surpluses	586,425	795,887
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(1,434,694)	(2,707,537)
Total retained earnings	(1,434,694)	(2,707,537)
Treasury shares	(142)	(142)
Total shareholders' equity	2,151,589	1,297,670
Share acquisition rights	7,680	24,088
Total net assets	2,159,269	1,321,759
Total liabilities and net assets	2,650,959	1,775,899

(2) Quarterly Statements of Income

Nine Months Ended September 30

(Thousand yen)

	For the nine months ended September 30, 2022	For the nine months ended September 30, 2023
Net sales	784,509	63,038
Cost of sales	474,357	32,433
Gross profit	310,152	30,604
Selling, general and administrative expenses	1,247,533	1,341,643
Operating loss	(937,381)	(1,311,038)
Non-operating income		
Interest income	458	1,007
Dividend income	–	3
Subsidy income	–	2,953
Foreign exchange gains	100,147	47,674
Other	40	177
Total non-operating income	100,646	51,816
Non-operating expenses		
Interest expenses	3,013	2,779
Amortization of restricted stock remuneration	14,676	629
Share issuance costs	30	8,155
Total non-operating expenses	17,720	11,563
Ordinary loss	(854,455)	(1,270,785)
Extraordinary income		
Gain on sale of bonds	21,406	–
Gain on sale of non-current assets	–	136
Total extraordinary income	21,406	136
Loss before income taxes	(833,049)	(1,270,649)
Income taxes - current	2,199	2,193
Total income taxes	2,199	2,193
Loss	(835,248)	(1,272,843)

(3) Notes to Quarterly Financial Statements

(Notes on going concern assumption)

There is no relevant information.

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

The Company received payments for the exercise of share acquisition rights during the period from July 25, 2023 to September 30, 2023. As a result, capital stock and legal capital surplus each increased by ¥209,462 thousand during the nine months ended September 30, 2023. At the end of the period, capital stock was ¥3,209,462 thousand and legal capital surplus was ¥795,887 thousand.

(Segment information, etc.)

[Segment information]

I. For the nine months ended September 30, 2022

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

II. For the nine months ended September 30, 2023

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

(Revenue recognition)

Disaggregation of revenue from contracts with customers

(Thousand yen)

	For the nine months ended September 30, 2022	For the nine months ended September 30, 2023
Goods / Services transferred at a point in time	63,075	63,038
Goods / Services transferred over time	721,434	–
Revenue from contracts with customers	784,509	63,038
Revenue from other sources	–	–
Net sales to outside customers	784,509	63,038

(Significant subsequent events)

There is no relevant information.

3. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the nine months ended September 30, 2023 totaled ¥897,337 thousand for the drug discovery business. The status of research and development activities during the nine months ended September 30, 2023 is as follows.

(1) Research and development structure

As of September 30, 2023, 18 persons belonged to research and development department, accounting for 47.3% 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. With the top-line data and other clinical safety data, we plan to submit a new drug application in Japan in 2024. We are also planning to make progress in viral production development on a commercial scale and to commence manufacturing for process validation in November 2023. Furthermore, we have been preparing to establish our own manufacturing and sales system which is suitable for the handling of Telomelysin, and we are proceeding with due diligence and negotiations on terms and conditions for an alliance with companies that are candidates to be our marketing partners.

Meanwhile, in overseas, we confirmed agreements in September 2023 on the establishment of a joint development system using Telomelysin and immune checkpoint inhibitors in the U.S. between Cornell University and the Company and between Cornell University and a U.S. major pharmaceutical company that markets immune checkpoint inhibitors. We are currently preparing for a clinical trial to begin in 2024.

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."

2. 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 or moderate and 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.

In addition, 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 plan to begin process validation in November 2023 and commercial manufacturing in 2024, when the new drug application will be submitted.

It is necessary to develop a system in which Telomelysin is imported into Japan and transported smoothly to medical institutions in compliance with the GMP Ministerial Ordinance after it is formulated by Henogen. The Company plans to conclude an agreement with a manufacturing base in Japan engaging in the storage of formulated Telomelysin after final packaging by March 2024. We also began the validation of quality tests so that Eurofins Analytical Science Laboratories (Kyoto City), with which we signed a contract in June 2023, and our Kobe Research Lab will be able to conduct quality tests necessary to make a final determination for shipment of Telomelysin. Furthermore, to ensure efficient sales in Japan of Telomelysin of which a final determination for shipment is made, we are undertaking negotiations to form a marketing partnership with pharmaceutical companies and are aiming to conclude an agreement by the end of 2023.

The Company will be positioned as an original distributor of Telomelysin shipping it to Japan even after the marketing partnership agreement is made between the Company and pharmaceutical companies. We therefore need to obtain a license for manufacturing and marketing pharmaceuticals by meeting all three requirements of "personal requirements," "GQP (Good Quality Practice)," and "GVP (Good Vigilance Practice)" by having regulatory authorities examine the system to take responsibility as a company in addition to Telomelysin's efficacy and safety and its production method and management system.

We have so far recruited staff to meet personal requirements and already appointed a quality assurance manager and safety management manager. The personal requirements are expected to be met by appointing a marketing director to structure the organization. We will also enhance GQP and GVP and apply to the Tokyo Metropolitan Government to certify that the Company is capable of undertaking the ultimate responsibility for Telomelysin in the market as well as responsibility for quality assurance and safety management, and obtain a license for manufacturing and marketing pharmaceuticals by submitting an approval application for Telomelysin.

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 inhibitors 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 a major pharmaceutical company in the U.S. after obtaining the prior agreement of the Company. In September 2023, agreements were concluded between the Company and Cornell University and between Cornell University and the U.S. major pharmaceutical company to confirm a basic agreement on the establishment of a joint development system. The Company will provide Telomelysin, and the U.S. major pharmaceutical company will provide immune checkpoint inhibitors to Cornell University. In addition, the expenses for the clinical trial will be shared equally between the Company and the U.S. major pharmaceutical company. 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. In addition, administration for the second stage began in fall 2023. 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 nucleoside reverse transcriptase 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 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. Although we have received a report from Transposon on the results of the interim analysis, the details of the analysis are yet to be disclosed at this time due to the request of Transposon, being concerned about the risk of other competitors entering into the field if the data is disclosed. To date, there have been no reports of safety problems that necessitate the termination of the trials.

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 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.

4) 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 carries the powerful 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.

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 (Enrollment complete)
		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	U.S.	Phase II
	Hepatocellular cancer (HCC)	Anti-PD-L1 antibody atezolizumab Molecular targeting drug	Japan	Phase I (complete)
		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-2011	Viral infectious diseases	TBD	Japan	Pre-clinical
OBP-702	Solid tumor	Anti-PD-(L)1 antibody (expected)	Japan	Pre-clinical
TelomeScan (OBP-401)	Solid tumor	—	Japan	Clinical research
OBP-801	Suppression of filtering bleb fibrosis after glaucoma surgery	Monotherapy	Japan	Pre-clinical