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, 2022 [Japanese GAAP]

November 4, 2022

Company name: Oncolys BioPharma Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4588
URL: http://www.oncolys.com
Representative: Yasuo Urata, President & CEO
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Scheduled date of filing quarterly securities report: November 4, 2022
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, 2022 (January 1, 2022 to September 30, 2022)

(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, 2022	784	-	(937)	-	(854)	-	(835)	-
September 30, 2021	318	53.3	(963)	-	(976)	-	(979)	-

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2022	(48.20)	-
September 30, 2021	(58.42)	-

(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.

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of September 30, 2022	3,455	2,472	71.3
As of December 31, 2021	4,291	3,593	83.6

(Reference) Equity: As of September 30, 2022: ¥2,465 million
As of December 31, 2021: ¥3,586 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, 2021	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2022	-	0.00	-		
Fiscal year ending December 31, 2022 (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, 2022 (January 1, 2022 to December 31, 2022)

(% indicates changes from the previous corresponding period for the full year.)

	Net sales		Operating profit		Ordinary profit		Profit		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
Full year	1,000	-	(1,600)	-	(1,600)	-	(1,600)	-	(94.59)

(Note) Revision to the financial results forecast announced most recently: No

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 figures of the financial results forecast above are the figures calculated after the application of the accounting standard, etc., the Company does not present the percentage of change from the previous corresponding period.

*** 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: Yes
2) Changes in accounting policies other than 1) above: No
3) Changes in accounting estimates: No
4) Retrospective restatement: No

(Note) For details, please see "2. Quarterly Financial Statements and Primary Notes (3) Notes to Quarterly Financial Statements (Changes in accounting policies)" on page 7 of the supplementary material.

(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, 2022: 17,405,200 shares
December 31, 2021: 17,405,200 shares

2) Total number of treasury shares at the end of the period:
September 30, 2022: 80,538 shares
December 31, 2021: 68,494 shares

3) Average number of shares during the period:
Nine months ended September 30, 2022: 17,328,525 shares
Nine months ended September 30, 2021: 16,770,384 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.

Table of Contents

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

(1) Explanation of Business Results

The Company has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020; hereinafter "Revenue Recognition Standard"), etc. from the beginning of the three months ended March 31, 2022. Therefore, the net sales in the following explanation of business results are explained without showing the amount of increase or decrease and year-on-year comparison (%).

During the nine months ended September 30, 2022, the Japanese economy remained sluggish owing to the rapid depreciation of the yen that resulted from interest rate differences between Japan and other countries, as well as continuing rising prices. The global economy, on the other hand, looks rather uncertain on the back of accelerating inflation, despite tightening money policies by major countries excluding Japan, and the impact of Russia's invasion of Ukraine, making it difficult to have a clear future outlook.

Amid these circumstances, the Company has been pursuing a vision of "Dedicating power 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 such activities with the aim of "virus drug discovery" within the business fields of "virotherapy for cancer" and "drugs for the treatment of serious viral infectious diseases." With regards to OBP-601 (Censavudine), a nucleoside reverse transcriptase inhibitor, its licensee Transposon Therapeutics, Inc. (hereinafter "Transposon") is conducting multiple clinical trials in Europe and the U.S. entirely at its own expense.

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, 2022, net sales were ¥784,509 thousand (net sales of ¥318,317 thousand in the same period of the previous year), and operating loss was ¥937,381 thousand (operating loss of ¥963,649 thousand in the same period of the previous year). During the same period, the Company recorded interest income of ¥458 thousand, foreign exchange gains of ¥100,147 thousand, and other items as non-operating income and interest expenses of ¥3,013 thousand, amortization of restricted stock remuneration of ¥14,676 thousand, share issuance costs of ¥30 thousand, and other items as non-operating expenses. As a result, ordinary loss was ¥854,455 thousand (ordinary loss of ¥976,891 thousand in the same period of the previous year). On the other hand, extraordinary profit of ¥21,406 thousand was recorded by selling the convertible bonds of Unleash Immuno Oncolytics, Inc. (Missouri, U.S.; hereinafter "Unleash") to Unleash. As a result, loss was ¥835,248 thousand (loss of ¥979,679 thousand in the same period of the previous year).

(2) Explanation of Financial Position

Assets at the end of the third quarter of the fiscal year under review were ¥3,455,544 thousand (19.5% decrease compared with the previous fiscal year-end), primarily owing to a decrease in cash and deposits. Liabilities were ¥982,585 thousand (40.8% increase compared with the previous fiscal year-end), primarily owing to an increase in contract liabilities. Net assets were ¥2,472,958 thousand (31.2% decrease compared with the previous fiscal year-end), owing to net loss incurred, as well as other factors.

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

For the fiscal year ending December 31, 2022, the Company forecasts net sales of ¥1,000 million, operating loss, ordinary loss, and net loss of ¥1,600 million, respectively. The Company also forecasts research and development expenses of ¥1,700 million for the fiscal year ending December 2022.

In June 2020, the Company signed an OBP-601 license agreement with Transposon. For the fiscal year ending December 31, 2022, the Company conducts business activities, aiming to sign new business alliance agreements as well. With regards to R&D activities, we are actively promoting clinical trials and nonclinical studies for various pipelines, manufacturing of investigational drugs, and development of new manufacturing methods for launch in Japan and overseas, with a focus on activities related to filing for approval of Telomelysin virotherapy for cancer by 2024.

The plan is to allocate funds raised in past years, as well as business income from the existing OBP-601 license agreement and new alliance agreements, for the funds required for these R&D and business activities.

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousand yen)

	As of December 31, 2021	As of September 30, 2022
Assets		
Current assets		
Cash and deposits	3,454,714	2,416,314
Accounts receivable – trade	352,148	182,569
Finished goods	8,434	8,434
Supplies	3,222	2,831
Advance payments – other	234,014	538,552
Prepaid expenses	120,977	56,747
Short-term loans receivable from subsidiaries and associates	-	43,443
Accounts receivable – other	4,179	65,862
Income taxes refund receivable	-	30,812
Consumption taxes receivable	20,304	61,117
Advances paid	-	33
Other	12	60
Total current assets	4,198,008	3,406,777
Non-current assets		
Property, plant and equipment		
Buildings	2,794	2,794
Accumulated depreciation	(2,794)	(2,794)
Buildings, net	-	-
Tools, furniture and fixtures	65,024	69,620
Accumulated depreciation	(65,024)	(65,439)
Tools, furniture and fixtures, net	-	4,180
Total property, plant and equipment	-	4,180
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	34,503	-
Lease and guarantee deposits	21,220	21,149
Long-term prepaid expenses	17,090	2,381
Other	19	19
Total investments and other assets	93,868	44,585
Total non-current assets	93,868	48,766
Total assets	4,291,876	3,455,544

(Thousand yen)

	As of December 31, 2021	As of September 30, 2022
Liabilities		
Current liabilities		
Short-term loans payable	238,880	227,776
Lease obligations	2,674	3,561
Accounts payable – other	106,247	483,433
Accrued expenses	16,846	12,956
Income taxes payable	59,242	-
Contract liabilities	-	40,021
Deposits received	6,320	26,958
Total current liabilities	430,211	794,707
Non-current liabilities		
Long-term loans payable	255,544	172,212
Lease obligations	6,372	7,661
Provision for retirement benefits	5,756	8,005
Total non-current liabilities	267,673	187,878
Total liabilities	697,884	982,585
Net assets		
Shareholders' equity		
Capital stock	9,039,516	3,000,000
Capital surplus		
Legal capital surplus	9,031,904	586,425
Other capital surplus	31,740	-
Total capital surpluses	9,063,645	586,425
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(14,516,735)	(1,121,004)
Total retained earnings	(14,516,735)	(1,121,004)
Treasury shares	(113)	(142)
Total shareholders' equity	3,586,312	2,465,278
Share acquisition rights	7,680	7,680
Total net assets	3,593,992	2,472,958
Total liabilities and net assets	4,291,876	3,455,544

(2) Quarterly Statements of Income

Nine Months Ended September 30

(Thousand yen)

	For the nine months ended September 30, 2021	For the nine months ended September 30, 2022
Net sales	318,317	784,509
Cost of sales	148,936	474,357
Gross profit	169,380	310,152
Selling, general and administrative expenses	1,133,029	1,247,533
Operating loss	(963,649)	(937,381)
Non-operating income		
Interest income	382	458
Foreign exchange gains	28,541	100,147
Other	779	40
Total non-operating income	29,703	100,646
Non-operating expenses		
Interest expenses	3,191	3,013
Amortization of restricted stock remuneration	28,116	14,676
Share acquisition rights issuance costs	413	-
Share issuance costs	11,007	30
Other	217	0
Total non-operating expenses	42,945	17,720
Ordinary loss	(976,891)	(854,455)
Extraordinary income		
Gain on sale of bonds	-	21,406
Total extraordinary income	-	21,406
Loss before income taxes	(976,891)	(833,049)
Income taxes - current	2,787	2,199
Total income taxes	2,787	2,199
Loss	(979,679)	(835,248)

(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)

In accordance with the resolution passed at the Annual General Meeting of Shareholders held on March 30, 2022, the capital reduction became effective on May 31, 2022. Accordingly, capital stock and legal capital surplus have been reduced by ¥6,039,516 thousand and ¥8,445,478 thousand, respectively, and the amounts have been transferred to other capital surplus. As a result, capital stock amounted to ¥3,000,000 thousand and legal capital surplus amounted to ¥586,425 thousand at the end of the third quarter of the fiscal year under review.

(Changes in accounting policies)

Nine Months Ended September 30, 2022 (from January 1, 2022 to September 30, 2022)
(Adoption of Accounting Standard for Revenue Recognition) The Company has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020; hereinafter "Revenue Recognition Standard"), etc. from the beginning of the first quarter of the fiscal year under review. The Company recognizes revenue when control of a promised good or service is transferred to a customer in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods and services. Previously, the Company had recognized the total amount of development cooperation money received from joint development partners as income and cost of sales at the time of billing. With the application of the Revenue Recognition Standard, the Company adopted the method of recognizing only the development expenses at the net amount. In addition, the Company had previously recognized the revenues from a contractual lump-sum payment, the milestone revenue payment, sales of investigational drugs, and manufacturing method development contributions based on an out-licensing contract at the time of the confirmation of billing or at a specific point in time during the acceptance inspection based on the license agreement. However, for the first quarter of the fiscal year under review, the Company adopted the method of recognizing the revenue over a certain period of time according to the fulfillment of performance obligations related to the contract if any of the performance obligation related to the contractual lump-sum payment, the milestone revenue payment, sales of investigational drugs, and manufacturing method development contributions based on an out-licensing contract is not satisfied at a specific point in time. The Company applies the Revenue Recognition Standard, etc. in accordance with the transitional treatment provided for in the proviso to Paragraph 84 of the Revenue Recognition Standard. The cumulative impact of retrospectively applying the new accounting policies to prior periods is adjusted to retained earnings brought forward at the beginning of the first quarter of the fiscal year under review, with the new accounting policies applied from the beginning balance. However, the Company applies the method provided for in Paragraph 86 of the Revenue Recognition Standard, and does not apply the new accounting policies retrospectively to contracts for which substantially all revenue amounts had been recognized prior to the beginning of the first quarter of the fiscal year under review in accordance with the previous treatment. In addition, applying the method stipulated in proviso (1) to Paragraph 86 of the Revenue Recognition Standard, contract modifications that occurred prior to the beginning of the first quarter of the fiscal year under review were accounted for based on the terms of the contract after reflecting all contract modifications, with the cumulative impact adjusted to retained earnings brought forward at the beginning of the first quarter of the fiscal year under review. As a result of this change, for the nine months ended September 30, 2022, in comparison with the case where this accounting policy has not been applied, net sales increased by ¥86,616 thousand, cost of sales decreased by ¥154,721 thousand, selling, general and administrative expenses decreased by ¥17,082 thousand, and operating profit, ordinary profit, and profit before income taxes increased by ¥258,420 thousand, respectively. In addition, the beginning balance of retained earnings brought forward decreased by ¥285,756 thousand. In accordance with the transitional treatment set forth in Paragraph 89-2 of the Revenue Recognition Standard, figures for the previous period have not been reclassified based on the new presentation method. In accordance with the transitional treatment set forth in Paragraph 28-15 of the "Accounting Standards for Quarterly Financial Statements" (ASBJ Statement No. 12, March 31, 2020), information on the disaggregation of revenue from contracts with customers for the cumulative period of the previous third quarter is not presented. (Adoption of Accounting standard for Fair Value Measurement)

The Company has applied the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30, July 4, 2019; hereinafter "Fair Value Measurement Standard"), etc. from the beginning of the first quarter of the fiscal year under review, and will prospectively apply the new accounting policies stipulated by the Fair Value Measurement Standard, etc. in accordance with the transitional treatment provided in Paragraph 19 of the Fair Value Measurement Standard and Paragraph 44-2 of the "Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, July 4, 2019). This does not affect the quarterly consolidated financial statements.

(Segment information, etc.)

[Segment information]

I. For nine months ended September 30, 2021

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

II. For nine months ended September 30, 2022

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

Nine Months Ended September 30, 2022

(Thousand yen)

Goods / Services transferred at a point in time	63,075
Goods / Services transferred over time	721,434
Revenue from contracts with customers	784,509
Revenue from other sources	---
Net sales to outside customers	784,509

(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, 2022 totaled ¥787,080 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 September 30, 2022, 20 persons belonged to research and development department, equivalent to 52.6% 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 places the highest priority on completing the "Phase II clinical trial in combination with radiation therapy for esophageal cancer" for Telomelysin, which has been granted "SAKIGAKE designation" for regenerative medicine products in Japan, and plans to file for approval in Japan in 2024. We plan to complete the enrollment of patients for the clinical trial, in which we will reach the target number of patients if one more patient is enrolled, and file for approval in Japan all by ourselves, given the time that may be lost if, after taking over the clinical trial, including its facilities, from Chugai Pharmaceutical Co., Ltd. (hereinafter "Chugai"), we hand over the clinical trial to another pharmaceutical company. On the manufacturing front, we have made steady progress in test manufacturing on a commercial manufacturing scale and the validation of formulation and quality tests. On the business front, we are conducting due diligence on several possible candidates for a marketing partner, with whom we plan to form an alliance after Telomelysin is approved. Overseas, we are promoting relicensing activities by proposing a clinical trial design that leverages the orphan drug designation granted by the U.S. Food and Drug Administration (FDA).

Currently, the following four clinical trials are underway in Japan and overseas:

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 I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer; and
iv) Phase I investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for solid tumors

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, and administration by Chugai to the first patient began in Japan in March 2020. Even after the decision to terminate the license contract in October 2021, the enrollment of patients is proceeding smoothly, with administration reaching the target number of patients if one more patient is enrolled. The Company aims to begin administration to the last patient for this clinical trial by the end of 2022.

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 to the first patient began in May 2019 led by Cornell University in the U.S. An evaluation of the efficacy and safety of Telomelysin and pembrolizumab will be performed for the most advanced stage IV patients. So far, three of all patients that have received administration showed partial response, and we plan to enroll up to 18 patients at the discretion of the investigator as this is an investigator-initiated clinical trial. We are planning to put together the findings by the end of this year so that we can report the findings at an academic conference at an early date. We are also speaking with mega pharmaceutical companies about a new trial plan for stomach cancer and other indications.

Regarding the above iii) “Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer,” NRG Oncology, a leading cancer research group in the U.S., has been leading the trial, and administration to the first patient began in December 2021. This clinical trial is conducted with the primary purpose of confirming the safety of using Telomelysin in combination with chemoradiotherapy. Thus far, Telomelysin has been administered to three patients with esophageal cancer and there have been no reports of problematic side-effects. Telomelysin has been designated as an orphan drug in the U.S., and this clinical trial will be conducted on that basis. Therefore, in addition to being able to consult with the FDA for advice in conducting clinical trials, the Company will be able to receive preferential treatment in the form of grants and tax credits for clinical research expenses. In addition, first-mover rights protection will be granted for seven years after the approval of Telomelysin in the U.S. and market exclusivity will be granted during that period.

Regarding the above iv) “Phase I investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for solid tumors,” administration to patients began in December 2017, led by the National Cancer Center Hospital East. As a result of the Phase Ia and Phase Ib clinical trials in a total of 22 patients, the safety of Telomelysin in combination with pembrolizumab and the efficacy in local esophageal cancer for some patients, were shown. Currently, with the enrollment of new patients being completed, we are analyzing biomarkers using clinical samples and conducting animal studies for further confirmation. We had intended to publish a report on these trials at an academic conference by the end of fiscal 2022, but the original plan has been postponed and we are now planning to present the report at the American Association for Cancer Research (AACR) Annual Meeting in the U.S. in April 2023. This is an investigator-initiated clinical trial, and the Company refrains from intervening with the content of the presentation.

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 promoted its development up to the completion of Phase II clinical trials as a treatment drug for HIV infection. The license agreement, however, was terminated due to changes in BMS’s business strategy. Later on, in June 2020, the Company concluded a new license agreement with Transposon totaling over $300 million primarily for intractable neurological diseases. Transposon achieved its first milestone in November 2020. Transposon is currently conducting to Phase IIa clinical trials, one on progressive supranuclear palsy (PSP) and the other on amyotrophic lateral sclerosis (ALS) and frontotemporal degeneration (FTD) at ten or more clinical trial facilities each in Europe and the U.S. Administration to the first patient under the Phase IIa clinical trial for PSP began in November 2021, and reached the target number of patients. Administration to the first patient under the Phase IIa clinical trial for ALS and FTD also began in January 2022. Both trials are conducted in a double-blind, placebo-controlled setting. So far, there have been no reports of safety problems that necessitate the termination of the trials. Results from these trials are expected to be reported by 2024. The above-mentioned clinical trials on OBP-601 by Transposon have been proceeding entirely at its own expense. Transposon is a company concentrating its efforts to develop OBP-601, and so we believe that the risk of OBP-601 being left in mothballs is low.

3) Activities related to OBP-2011 for the treatment of COVID-19

From the experimental outcomes, the Company assumes that its OBP-2011 is a nucleocapsid inhibitor. The orally administered COVID-19 treatments currently under development by pharmaceutical companies around the world tend to rely on a polymerase or protease inhibitor mechanism. On the other hand, OBP-2011 has a different, newer mechanism. It is expected that its effect 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. Given these circumstances, the Company will proceed with the identification of target proteins for solving the detailed mechanism of action for OBP-2011 by conducting collaborative research with Kagoshima University and the National Institute of Infectious Diseases and pursue a framework for joint development with pharmaceutical companies.

4) Activities related to next generation Telomelysin (OBP-702)

OBP-702 has two anti-tumor effects which combine the "oncogene therapy" of the powerful cancer suppressor gene p53 with the "oncolytic functions" of Telomelysin (OBP-301). In addition, a research group led by Professor Toshiyoshi Fujiwara of the Department of Gastroenterological Surgery, Transplant, and Surgical Oncology of Okayama University conducted non-clinical trials on OBP-702, which was adopted as a grant program by the Japan Agency for Medical Research and Development (AMED), and reported on results of those trials at many conferences. In particular, in 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 than either of them administered alone. It is expected that OBP-702 will be developed as a new treatment method for pancreatic cancer and other refractory cancers.

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. The Company conducted a joint development agreement with K.K. CYBO in March 2022 and is proceeding with the development of automatic detection software using AI technology, aiming to not only reduce the time for processing test results but also improve the sensitivity and specificity of CTC detection and bring this platform to practical use in Japan.

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 was observed in Phase I clinical trials in the U.S., and thus, at present, development in the field of cancer has been suspended. On the other hand, research for application to glaucoma surgery is being continued 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.

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
		Chemoradiotherapy	U.S.	Phase I
		Anti-PD-1 antibody pembrolizumab	Japan	Phase I (complete)
	Gastric/ gastroesophageal junction cancer	Anti-PD-1 antibody pembrolizumab	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)
	Head and neck cancer	Anti-PD-1 antibody pembrolizumab Radiation therapy	U.S.	Phase II (complete)
OBP-601 (Censavudine)	Amyotrophic lateral sclerosis (ALS) / frontotemporal degeneration (FTD)	TBD	U.S.	Phase IIa
	Progressive supranuclear palsy (PSP)	TBD	U.S.	Phase IIa
OBP-2011	Novel coronavirus infection (COVID-19)	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	Ophthalmic field	—	Japan	Pre-clinical