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 Three Months Ended March 31, 2022 [Japanese GAAP]

May 13, 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: May 13, 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 Three Months Ended March 31, 2022 (January 1, 2022 to March 31, 2022)

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

	Net sales		Operating profit		Ordinary profit		Profit	
Three months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
March 31, 2022	193	-	(384)	-	(349)	-	(328)	-
March 31, 2021	62	(10.9)	(349)	-	(349)	-	(350)	-

	Basic earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
March 31, 2022	(18.98)	-
March 31, 2021	(22.36)	-

(Note) The Company has applied the Accounting Standard for Revenue Recognition (ASBJ Statement No. 29 of March 31, 2020), etc. from the beginning 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 three months ended March 31, 2022 from the previous corresponding period.

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of March 31, 2022	3,856	2,979	77.1
As of December 31, 2021	4,291	3,593	83.6

(Reference) Equity: As of March 31, 2022: ¥2,971 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	-				
Fiscal year ending December 31, 2022 (Forecast)		0.00	-	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 of March 31, 2020), etc. from the beginning 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, 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):
March 31, 2022: 17,405,200 shares
December 31, 2021: 17,405,200 shares

2) Total number of treasury shares at the end of the period:
March 31, 2022: 73,494 shares
December 31, 2021: 68,494 shares

3) Average number of shares during the period:
Three months ended March 31, 2022: 17,332,511 shares
Three months ended March 31, 2021: 15,677,731 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 3 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

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 three months ended March 31, 2022, the Japanese economic activities slowed down due to prolonged self-restraint due to COVID-19 and soaring prices of crude oil although the quasi-emergency measures were lifted. In addition, the outlook for the world economy is highly uncertain because of the rapid appreciation of the U.S. dollar against the euro and Japanese yen due to the invasion of Ukraine and the concerns on inflation caused by the economic sanctions for Russia and rising resource prices such as crude oil, etc., and it is difficult to determine their impact on the world economy.

Under 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.”, increased management efficiency and actively expanded its 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 and OBP-2011 for the treatment of COVID-19, aiming for "virus drug discovery" with the business fields of "virotherapy for cancer" and "drugs for the treatment of serious viral infectious diseases.” In addition, concerning OBP-601 (Censavudine), a nucleoside reverse transcriptase inhibitor, 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 “3. Supplemental Information (1) Research and development activities.”

For the three months ended March 31, 2022, net sales were ¥193,125 thousand (net sales of ¥62,603 thousand in the same period of the previous year) and operating loss was ¥384,747 thousand (operating loss of ¥349,453 thousand in the same period of the previous year). In addition, the Company recorded interest income of ¥153 thousand, foreign exchange gains of ¥39,380 thousand, and other items as non-operating income and interest expenses of ¥864 thousand, amortization of restricted stock remuneration of ¥3,520 thousand, share issuance costs of ¥30 thousand, and other items as non-operating expenses. As a result, ordinary loss was ¥349,628 thousand (ordinary loss of ¥349,626 thousand in the same period of the previous year). On the other hand, an extraordinary profit of ¥21,406 thousand was recorded by selling the convertible bonds of Unleash Immuno Oncolytics, Inc. (Missouri, USA, hereinafter referred to as “Unleash”) to Unleash. As a result, loss was ¥328,960 thousand (loss of ¥350,567 thousand in the same period of the previous year).

(2) Explanation of Financial Position

Status of Assets, Liabilities and Net Assets

Assets at the end of the first quarter of the fiscal year under review were ¥3,856,416 thousand (10.1% decrease compared with the end of the previous fiscal year), owing partly to an decrease in cash and deposits. Liabilities were ¥877,140 thousand (25.7% increase compared with the end of the previous fiscal year), owing partly to increase of accounts payable - other. Net assets were ¥2,979,275 thousand (17.1% decrease compared with the end of the previous fiscal year), owing to loss incurred and 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. The Company also forecasts research and development expenses of 1,700 million yen for the fiscal year ending December 31, 2022.

These forecast are based on assumed rates of ¥115 per U.S. dollar and ¥130 per euro.

The Company has signed new licensing agreements, including an OBP-601 license agreement with Transposon in June 2020. In the fiscal year ending December 31, 2022, the Company plans to sign new license agreements in terms of business. In R&D activities, we will actively promote clinical trials of various pipelines, nonclinical studies, investigational drug manufacturing, and manufacturing method development for launch, in Japan and overseas, focusing on Telomelysin and OBP-2011 for the treatment of COVID-19. The plan is to allocate funds raised in the past years for the funds required for these R&D and business activities.

Since the Company manages its performance annually, the Company omits the description of its earnings forecasts for the second quarter (cumulative).

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousand yen)

	As of December 31, 2021	As of March 31, 2022
Assets		
Current assets		
Cash and deposits	3,454,714	3,222,045
Accounts receivable – trade	352,148	66,318
Finished goods	8,434	8,434
Supplies	3,222	3,093
Advance payments – other	234,014	272,605
Prepaid expenses	120,977	84,568
Short-term loans receivable from subsidiaries and associates	-	24,482
Accounts receivable – other	4,179	37,072
Consumption taxes receivable	20,304	70,234
Advances paid	-	646
Other	12	11
Total current assets	4,198,008	3,789, 514
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	65,660
Accumulated depreciation	(65,024)	(65,053)
Tools, furniture and fixtures, net	-	607
Total property, plant and equipment	-	607
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	12,241
Lease and guarantee deposits	21,220	21,149
Long-term prepaid expenses	17,090	11,848
Other	19	19
Total investments and other assets	93,868	66,293
Total non-current assets	93,868	66,901
Total assets	4,291,876	3,856,416

(Thousand yen)

	As of December 31, 2021	As of March 31, 2022
Liabilities		
Current liabilities		
Short-term loans payable	238,880	216,664
Lease obligations	2,674	2,689
Accounts payable – other	106,247	175,359
Accrued expenses	16,846	12,283
Income taxes payable	59,242	5,443
Contract liabilities	-	213,856
Advances received	-	-
Deposits received	6,320	5,982
Total current liabilities	430,211	632,278
Non-current liabilities		
Long-term loans payable	255,544	233,328
Lease obligations	6,372	5,694
Provision for retirement benefits	5,756	5,838
Total non-current liabilities	267,673	244,861
Total liabilities	697,884	877,140
Net assets		
Shareholders' equity		
Capital stock	9,039,516	9,039,516
Capital surplus		
Legal capital surplus	9,031,904	9,031,904
Other capital surplus	31,740	31,740
Total capital surpluses	9,063,645	9,063,645
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(14,516,735)	(15,131,452)
Total retained earnings	(14,516,735)	(15,131,452)
Treasury shares	(113)	(113)
Total shareholders' equity	3,586,312	2,971,595
Share acquisition rights	7,680	7,680
Total net assets	3,593,992	2, 979,275
Total liabilities and net assets	4,291,876	3,856,416

(2) Quarterly Statements of Income

Three Months Ended March 31

(Thousand yen)

	For the three months ended March 31, 2021	For the three months ended March 31, 2022
Net sales	62,603	193,125
Cost of sales	35,427	65,641
Gross profit	27,175	127,483
Selling, general and administrative expenses	376,629	512,231
Operating loss	(349,453)	(384,747)
Non-operating income		
Interest income	131	153
Foreign exchange gains	25,702	39,380
Other	682	-
Total non-operating income	26,516	39,533
Non-operating expenses		
Interest expenses	932	864
Amortization of restricted stock remuneration	14,220	3,520
Share acquisition rights issuance costs	413	-
Share issuance costs	10,905	30
Other	217	-
Total non-operating expenses	26,689	4,415
Ordinary loss	(349,626)	(349,628)
Extraordinary income		
Gain on sale of bonds	-	21,406
Total extraordinary income	-	21,406
Loss before income taxes	(349,626)	(328,222)
Income taxes – current	941	738
Total income taxes	941	738
Loss	(350,567)	(328,960)

(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)

There is no relevant information.

(Changes in accounting policies)

Three Months Ended March 31, 2022 (from January 1, 2022 to March 31, 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 three months ended March 31, 2022, in comparison with the case where this accounting policy has not been applied, net sales decreased by ¥38,495 thousand, cost of sales decreased by ¥41,199 thousand, selling, general and administrative expenses decreased by ¥5,694 thousand, and operating profit, ordinary profit, and profit before income taxes increased by ¥85,389 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 first 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 three months ended March 31, 2021

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

II. For three months ended March 31, 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

Three Months Ended March 31, 2022

(Thousand yen)

Goods / Services transferred at a point in time	36,287
Goods / Services transferred over time	156,838
Revenue from contracts with customers	193,125
Revenue from other sources	—
Net sales to outside customers	193,125

3. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the three months ended March 31, 2021 totaled ¥347,834 thousand for the drug discovery business. The status of research and development activities for the drug discovery business during the fiscal year under review is as follows.

(1) Research and development structure

As of March 31, 2022, 16 persons belonged to research and development department, equivalent to 44.4% of the total number of employees.

(2) Research and development and business activities

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

1) Activities related to Telomelysin (OBP-301) (International Nonproprietary Name: suratadenoturev) virotherapy for cancer

In December 2021, the Company agreed on a license termination contract for Telomelysin with Chugai Pharmaceutical Co., Ltd. (hereinafter "Chugai"). In accordance with this contract, the Company will take over the Phase II esophageal cancer clinical trials by October 15, 2022, which Chugai is currently implementing in Japan. In the time up until that date, Chugai will proceed with the ongoing clinical trials at its own expense. In addition, regarding the costs related to GMP production development for Telomelysin, Chugai will bear approximately 50% of the costs of the invoice amount received by the Company from the contract manufacturer by October 15, 2022.

As of March 31, 2022, the following six clinical trials are under way in Japan and overseas:

i) Phase II clinical trial in combination with radiation therapy for esophageal cancer;
ii) Phase I clinical trial in combination with atezolizumab, an anti-PD-L1 antibody, and bevacizumab, a molecular targeting drug, for hepatocellular cancer;
iii) Phase II investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for gastric cancer/gastroesophageal junction cancer;
iv) Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer;
v) Phase II investigator-initiated clinical trial in combination with radiation therapy and pembrolizumab, an anti-PD-1 antibody, for head and neck cancer; and
vi) Phase I investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for solid tumors

Going forward, the Company will place 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 aim to file for approval in Japan in 2024. Overseas, the Company will leverage the orphan drug designation by the U.S. Food and Drug Administration (FDA) to continue existing clinical trials while simultaneously promoting relicensing activities.

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. The targeted number of patients to be administered is 37, and even after the decision to terminate the license contract in October 2021, the enrollment of patients is proceeding smoothly. The Company will take over the clinical trial from Chugai by October 15, 2022. In the time up until that date, Chugai will proceed with the clinical trial at its own expense.

Regarding the above ii) "Phase I clinical trial in combination with atezolizumab, an anti-PD-L1 antibody, and bevacizumab, a molecular targeting drug, for hepatocellular cancer," administration to the first patient began in January 2021 by Chugai as the first clinical trial where Telomelysin is administered in combination with atezolizumab, an anti-PD-L1 antibody. However, as a result of discussion with Chugai, it is scheduled to end this clinical trial by October 2022. The Company and Chugai have confirmed that the reason for terminating this trial is not problems of safety and efficacy.

Regarding the above iii) "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, an anti-PD-1 antibody, will be performed for the most advanced stage IV patients. A meeting was held at the end of December 2020 to review interim progress of eight patients, for whom evaluation was possible. Evaluation for one patient indicated partial response (PR) and for another stable disease (SD). Local reaction, which does not happen when pembrolizumab alone is administered, was found for the patient who showed PR. It is considered highly likely that this is the effect of administering Telomelysin. There was no report of problematic side-effects. The Company is currently adding clinical trial facilities to accelerate enrollment of patients. The Company plans to conduct an interim evaluation of the progress in 18 patients by the end of 2022 and decide whether to continue with the clinical trial.

Regarding the above iv) "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 with a goal to enroll a maximum of 21 patients. 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 v) "Phase II investigator-initiated clinical trial in combination with radiation therapy and pembrolizumab, an anti-PD-1 antibody, for head and neck cancer," administration to the first patient began in May 2021, led by Cornell University in the U.S. In this clinical trial, the systemic clinical effects of Telomelysin used in combination with the anti-PD-1 antibody, in addition to the synergistic local effects of the Telomelysin used in combination with radiation therapy, will be examined. The Company plans to evaluate the progress of 12 patients by the end of 2022 and decide whether to continue with the clinical trial.

Regarding the above vi) "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 National Cancer Center Hospital East. As a result of the Phase Ia and Phase Ib clinical trials in a total 22 patients, the safety of Telomelysin in combination with pembrolizumab, an anti-PD-1 antibody, and the efficacy in local esophageal cancer for some patients, were shown. Currently, the enrollment of new patients has been completed. A report was received of a scheduled presentation of the content of the trial at ASCO-GI symposium in January 2022, but a report was received that the presentation had been postponed as it has been taking longer than imagined to analyze biomarkers associated with the clinical trial. This is an investigator-initiated clinical trial, and the Company refrains from checking the content of the presentation in advance.

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

The Company concluded a joint research agreement with Kagoshima University in 2006, and has promoted drug discovery research for various intractable viral diseases with a research group led by Director Masanori Baba of the Joint Research Center for Human Retrovirus Infection at Kagoshima University Campus. To date, OBP-2001 was discovered as a chemical compound fairly effective in suppressing the growth of SARS-CoV-2, which is the virus that causes COVID-19. Based on the results of pre-clinical trials, it has been confirmed that OBP-2011 can be orally administered.

While the mechanism of orally administered COVID-19 treatments under development by pharmaceutical companies around the world is polymerase or protease inhibitors, experimental outcomes suggest the Company's OBP-2011 is a nucleocapsid inhibitor, which inhibits virus assembly, which occurs in a late stage of the virus growth. It is a new mechanism that differs from those of other treatments under development. It is expected that its effect is not affected by such factors as virus mutation.

In vitro experiment, it exhibited efficacy against all of the Variants of Concern (VOCs) designated by the World Health Organization: alpha, gamma, delta, beta, and the Omicron variant. Moreover, the chemical compound was also confirmed to indicate the same level of activity for other coronaviruses, such as those that caused the outbreak of severe acute respiratory syndrome (SARS) in 2002 and Middle East respiratory syndrome (MERS) in 2012, as it does for the wild type, demonstrating effectiveness in suppressing the growth of a broad range of coronaviruses.

Currently, collaborative research is being conducted with the University of Tsukuba to evaluate the effectiveness of OBP-2011 using a mouse model of disease. In addition, another collaborative research is being conducted with the National Institute of Infectious Diseases for the purpose of solving the detailed

mechanism of action of OBP-2011. By summarizing the results of these collaborative research, the Company would like to conclude a new license agreement with a major pharmaceutical company, and prepare to respond to the next pandemic with this drug as a therapeutic drug that turns patients SARS-CoV-2 negative in a short period of time and can be orally administered.
The Company plans to submit a clinical trial notification for OBP-2011 in 2022 and start clinical trials in 2023.

3) 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 two Phase IIa clinical trials at its own full expense, one on progressive supranuclear palsy (PSP) and the other on amyotrophic lateral sclerosis (ALS) and frontotemporal degeneration (FTD). Administration to the first patient under the Phase IIa clinical trial for PSP began in November 2021. In addition, administration to the first patient under the Phase IIa clinical trial for ALS and FTD also began in January 2022. Both trials will be conducted in a double-blind, placebo-controlled setting, and results from these trials are expected to be reported by 2024.

The above-mentioned clinical trials on OBP-601 by Transposon have been proceeding at its own full expense.

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 Department of Gastroenterological Surgery of Okayama University conducted non-clinical trials on OBP-702, which was adopted as a grant program of the Japan Agency for Medical Research and Development (AMED), reporting on results of those trials at several conferences. In particular, in an experiment on a gemcitabine-resistant pancreatic cancer cell lines using mouse models, OBP-702 used in combination with PD-L1 antibodies exhibited stronger anti-tumor effects than OBP-702 or PD-L1 antibodies administered alone. It is expected that clinical trials for combined use with PD-L1 antibodies for pancreatic cancer will be conducted in the future.

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 concluded a joint development agreement with K.K. CYBO in March 2022 and is proceeding with the development of automatic detection software using clinical specimens. By making use of AI technology, the Company is aiming to not only reduce the time for processing test results but also improve the sensitivity of CTC image analysis and the specificity of the tests 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 is being continued at the Kyoto Prefectural University of Medicine in the ophthalmic field, which is a new area of indication for OBP-801.

The development status of pipeline is as follows.

Product	Indication	Combination therapy	Development region	Development stage
Telomelysin (OBP-301) (Suratadenoturev)	Esophageal cancer	Radiation therapy	Japan	Phase II (Chugai *1)
		Chemoradiotherapy	U.S.	Phase I
	Hepatocellular cancer (HCC)	Anti-PD-L1 antibody atezolizumab Molecular targeting drug	Japan	Phase I (Chugai *2)
		—	South Korea and Taiwan	Phase I (complete)
	Head and neck cancer	Anti-PD-1 antibody pembrolizumab Radiation therapy	U.S.	Phase II
	Gastric/ gastroesophageal junction cancer	Anti-PD-1 antibody pembrolizumab	U.S.	Phase II
	Esophageal cancer (solid tumor)	Anti-PD-1 antibody pembrolizumab	Japan	Phase I (complete)
OBP-2011	Novel coronavirus infection (COVID-19)	TBD	Worldwide	Pre-clinical
OBP-601 (Censavudine)	Amyotrophic lateral sclerosis (ALS) / frontotemporal degeneration (FTD)	TBD	U.S.	Phase IIa
	Progressive supranuclear palsy (PSP)	TBD	U.S.	Phase IIa
	HIV infection	—	Europe, the U.S. and others	Phase IIb (complete)
OBP-702	Solid tumor	Anti-PD-(L)1 antibody (expected)	U.S. / Japan	Pre-clinical
OBP-801	Solid tumor	Anti-PD-(L)1 antibody (expected)	U.S.	Phase I (complete)
	Ophthalmic field	—	Japan	Pre-clinical
TelomeScan (OBP-401)	Solid tumor	—	Japan	Clinical research

*1: Chugai is developing the product, but the Company will take over the development by October 15, 2022.
*2: Chugai is developing the product, but the development will be completed by October 15, 2022.