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 Six Months Ended June 30, 2021 [Japanese GAAP]

August 6, 2021

Company name: Oncolys BioPharma Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4588
URL: http://www.oncolys.com
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Scheduled date of filing quarterly securities report: August 6, 2021
Scheduled date of commencing dividend payments: —
Availability of supplementary briefing material on quarterly financial results: No
Schedule of quarterly financial results briefing session: Scheduled (for analysts)

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

1. Financial Results for the Six Months Ended June 30, 2021 (January 1, 2021 to June 30, 2021)

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

	Net sales		Operating profit		Ordinary profit		Profit	
Six months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
June 30, 2021	193	41.8	(633)	-	(649)	-	(650)	-
June 30, 2020	136	(78.1)	(660)	-	(662)	-	(664)	-

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
June 30, 2021	(39.45)	-
June 30, 2020	(46.43)	-

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of June 30, 2021	5,197	4,480	86.1
As of December 31, 2020	2,796	2,003	71.4

(Reference) Equity: As of June 30, 2021: ¥4,473 million
As of December 31, 2020: ¥1,995 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, 2020	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2021	-	0.00			
Fiscal year ending December 31, 2021 (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, 2021 (January 1, 2021 to December 31, 2021)

(% 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	350 ~ 700	111.4 ~ 222.9	(2,000) ~ (1,650)	-	(2,000) ~ (1,650)	-	(2,000) ~ (1,650)	-	(136.59) ~ (112.69)

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

*** 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):
June 30, 2021: 17,340,900 shares
December 31, 2020: 14,641,900 shares

2) Total number of treasury shares at the end of the period:
June 30, 2021: 34,962 shares
December 31, 2020: 14,462 shares

3) Average number of shares during the period:
Six months ended June 30, 2021: 16,498,589 shares
Six months ended June 30, 2020: 14,316,246 shares

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

<u>* Explanation of the proper use of financial results forecast and other notes</u>

(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 Japanese economy during the six months ended June 30, 2021, despite the concerns over consumer spending and hindrance in distribution systems arising under the threat of a global spread of COVID-19, has shown some signs of gradual recovery thanks to the rollout of vaccines and easing of restrictions on economic activities.

Amid these circumstances, Oncolys BioPharma Inc. (hereinafter "the Company") endeavored to increase management efficiency and actively expanded its research, development, and licensing activities in the drug discovery business. For details of the Company's activities, please refer to "3. Supplemental Information (1) Research and development activities."

The Company was previously composed of two reportable segments classified as the "pharmaceutical business" and the "diagnostic business." However, since more than 99% of net sales of the Company are from the pharmaceutical business and the trend is expected to continue, the Company changed the method of performance management and changed to a single segment of the "drug discovery business" from the first quarter of the fiscal year under review. Information by segment is therefore omitted.

In the drug discovery business during the six months ended June 30, 2021, Chugai Pharmaceutical Co., Ltd. (hereinafter "Chugai"), the licensee, pushed ahead with the clinical trial in Japan of Telomelysin virotherapy in combination with radiation therapy for esophageal cancer as well as a clinical trial for hepatocellular cancer. Furthermore, Chugai has also started recruiting patients for the clinical trial in combination with chemoradiotherapy for esophageal cancer. Meanwhile, the Company began administration to the first patient in the clinical trial for head and neck cancer in the U.S.

For OBP-2011 for the treatment of COVID-19, the Company concluded a joint research agreement with Shin Nippon Biomedical Laboratories, Ltd. (hereinafter "SNBL") with the aim of accelerating preclinical development and reducing the time to commencement of clinical trials. Together with Spera Nexus, Inc. (previously known as Iwaki Seiyaku Co., Ltd.), to whom the Company commissions GMP manufacturing of active pharmaceutical ingredients for investigational drugs, and also with SNBL, the Company is promoting activities with a view to applying in 2022 to conduct clinical trials.

As for TelomeScan, a cancer detection drug, the Company set up a "Collaborative Research Program on Minimally Invasive Cancer Detection Method Using TelomeScan" together with Juntendo University, with the aim of establishing a platform for automated detection of live Circulating Tumor Cells (CTC) within blood. The Company aims to develop a platform combining TelomeScan, which can detect high-grade live CTC within blood, and AI technology that can make detection more efficient, with an eye to completion by 2024 and subsequently, commercial application.

As a result, for the six months ended June 30, 2021, net sales were ¥193,067 thousand (net sales of ¥136,115 thousand in the same period of the previous year), and operating loss was ¥633,599 thousand (operating loss of ¥660,290 thousand in the same period of the previous year). In addition, the Company recorded interest income of ¥238 thousand, foreign exchange gains of ¥24,514 thousand, and other items as non-operating income and interest expenses of ¥2,109 thousand, amortization of restricted stock remuneration of ¥27,135 thousand, share issuance costs of ¥10,977 thousand, and other items as non-operating expenses. As a result, ordinary loss was ¥649,015 thousand (ordinary loss of ¥662,891 thousand in the same period of the previous year), and loss was ¥650,860 thousand (loss of ¥664,734 thousand in the same period of the previous year).

(2) Explanation of Financial Position

Assets at the end of the second quarter of the fiscal year under review were ¥5,197,403 thousand (85.9% increase compared with the end of the previous fiscal year), owing partly to a ¥2,579,157 thousand increase in

cash and deposits due to capital increase through issuance of new shares, a ¥40,168 thousand increase in accounts receivable – trade. Liabilities were ¥716,556 thousand (9.6% decline compared with the end of the previous fiscal year), owing partly to a decline in accounts payable – other. Net assets were ¥4,480,847 thousand (123.7% increase compared with the end of the previous fiscal year), owing to capital increase through issuance of new shares, loss incurred and other factors.

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

For the fiscal year ending December 31, 2021, the Company forecasts net sales of ¥350 million to ¥700 million, operating loss, ordinary loss, and net loss of ¥1,650 million to ¥2,000 million.

These forecasts are based on assumed rates of ¥110 per U.S. dollar and ¥134 per euro.

The Company has signed new licensing agreements, including a license agreement for Telomelysin with Chugai in April 2019 and an OBP-601 license agreement with Transposon in June 2020. The Company will continue to actively promote business activities aimed at concluding new contracts with major pharmaceutical companies, with a focus on the licensing activities of Telomelysin to the Chinese region and strive to increase corporate value.

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, OBP-2011 for the treatment of COVID-19, and OBP-702.

The plan is to allocate funds raised through the "Notice concerning the issuance of new shares and the 18th Stock Acquisition Rights (with exercise price amendments) through third party allotment and the conclusion of facility agreements (with suspension of exercise designation clauses)" announced on December 10, 2020 and business income.

However, due to the worldwide spread of COVID-19 infections, the proper and reasonable prospects for business and R&D activities are unclear. Therefore, the Company considered it appropriate to publish a range-style earnings forecast. 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, 2020	As of June 30, 2021
Assets		
Current assets		
Cash and deposits	2,067,927	4,647,084
Accounts receivable – trade	70,598	110,766
Finished goods	8,434	8,434
Supplies	2,038	2,546
Advance payments – other	43,354	59,387
Prepaid expenses	241,379	147,860
Accounts receivable – other	1,544	264
Consumption taxes receivable	95,445	12,459
Advances paid	14,935	5,227
Other	16	14
Total current assets	2,545,676	4,994,046
Non-current assets		
Property, plant and equipment		
Buildings	2,794	2,794
Accumulated depreciation	(2,794)	(2,794)
Buildings, net	—	—
Tools, furniture and fixtures	87,525	85,358
Accumulated depreciation	(66,207)	(63,324)
Tools, furniture and fixtures, net	21,317	22,033
Total property, plant and equipment	21,317	22,033
Intangible assets		
Software	650	550
Total intangible assets	650	550
Investments and other assets		
Investment securities	458	—
Shares of subsidiaries and associates	111,916	111,916
Investments in capital	100	100
Long-term loans receivable from subsidiaries and associates	31,050	33,183
Lease and guarantee deposits	21,229	21,300
Long-term prepaid expenses	63,996	14,254
Other	19	19
Total investments and other assets	228,769	180,773
Total non-current assets	250,736	203,357
Total assets	2,796,413	5,197,403

(Thousand yen)

	As of December 31, 2020	As of June 30, 2021
Liabilities		
Current liabilities		
Short-term loans payable	150,008	166,660
Lease obligations	2,144	2,644
Accounts payable – other	206,610	84,248
Accrued expenses	15,333	12,268
Income taxes payable	33,486	48,805
Deposits received	7,661	5,600
Total current liabilities	415,244	320,227
Non-current liabilities		
Long-term loans payable	366,648	383,324
Lease obligations	6,275	7,717
Provision for retirement benefits	4,920	5,287
Total non-current liabilities	377,843	396,329
Total liabilities	793,087	716,556
Net assets		
Shareholders' equity		
Capital stock	7,436,537	9,000,635
Capital surplus		
Legal capital surplus	7,428,925	8,993,023
Other capital surplus	31,740	31,740
Total capital surpluses	7,460,666	9,024,764
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(12,901,296)	(13,552,156)
Total retained earnings	(12,901,296)	(13,552,156)
Treasury shares	(76)	(76)
Total shareholders' equity	1,995,830	4,473,167
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	(254)	—
Total valuation and translation adjustments	(254)	—
Share acquisition rights	7,750	7,680
Total net assets	2,003,325	4,480,847
Total liabilities and net assets	2,796,413	5,197,403

(2) Quarterly Statements of Income

Six Months Ended June 30

(Thousand yen)

	For the six months ended June 30, 2020	For the six months ended June 30, 2021
Net sales	136,115	193,067
Cost of sales	34,661	53,516
Gross profit	101,453	139,551
Selling, general and administrative expenses	761,744	773,150
Operating loss	(660,290)	(633,599)
Non-operating income		
Interest income	10,047	238
Foreign exchange gains	—	24,514
Other	—	685
Total non-operating income	10,047	25,437
Non-operating expenses		
Interest expenses	2,001	2,109
Amortization of restricted stock remuneration	6,055	27,135
Share acquisition rights issuance costs	—	413
Share issuance costs	—	10,977
Foreign exchange losses	4,561	—
Other	30	217
Total non-operating expenses	12,648	40,853
Ordinary loss	(662,891)	(649,015)
Loss before income taxes	(662,891)	(649,015)
Income taxes - current	1,843	1,844
Total income taxes	1,843	1,844
Loss	(664,734)	(650,860)

(3) Quarterly Statements of Cash Flows

(Thousand yen)

	For the six months ended June 30, 2020	For the six months ended June 30, 2021
Cash flows from operating activities		
Loss before income taxes	(662,891)	(649,015)
Depreciation	2,056	3,054
Amortization of restricted stock remuneration	6,055	27,135
Loss (gain) on valuation of investment securities	—	226
Share-based remuneration expenses	93,185	156,659
Increase (decrease) in provision for retirement benefits	(295)	367
Interest and dividend income	(10,047)	(241)
Interest expenses	2,001	2,109
Foreign exchange losses (gains)	3,835	(13,442)
Decrease (increase) in notes and accounts receivable - trade	102,738	(40,168)
Decrease (increase) in inventories	4,827	(507)
Decrease (increase) in prepaid expenses	(8,852)	(40,530)
Decrease (increase) in accounts receivable - other	—	1,398
Increase (decrease) in accrued consumption taxes	(75,828)	83,295
Decrease (increase) in advance payments - other	1,032	(16,032)
Increase (decrease) in accounts payable - other	(157,266)	(122,086)
Other, net	(42,453)	22,715
Subtotal	(741,903)	(585,062)
Interest and dividend income received	836	136
Interest expenses paid	(2,430)	(2,387)
Income taxes paid	(3,718)	(4,657)
Net cash provided by (used in) operating activities	(747,216)	(591,970)
Cash flows from investing activities		
Proceeds from sale of investment securities	—	486
Purchase of property, plant and equipment	(1,225)	(743)
Payments for investments in capital of subsidiaries and associates	(10,763)	—
Long-term loan advances	(21,762)	—
Payments for lease and guarantee deposits	(2,451)	(71)
Net cash provided by (used in) investing activities	(36,201)	(327)
Cash flows from financing activities		
Proceeds from long-term loans payable	100,000	100,000
Repayments of long-term loans payable	(58,330)	(66,672)
Repayments of lease obligations	(1,726)	(1,294)
Proceeds from issuance of common shares	10,560	3,085,224
Proceeds from payment of deposits for subscriptions of shares	1,000	—
Proceeds from issuance of share acquisition rights	—	42,902
Purchase of treasury shares	(41)	—
Net cash provided by (used in) financing activities	51,462	3,160,160
Effect of exchange rate change on cash and cash equivalents	(3,432)	11,294
Net increase (decrease) in cash and cash equivalents	(735,387)	2,579,157
Cash and cash equivalents at beginning of year	3,097,514	1,822,850
Cash and cash equivalents at end of period	2,362,127	4,402,007

(4) 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 stock acquisition rights during the period from January 5, 2021 to May 19, 2021. As a result, capital stock and legal capital surplus each increased by ¥1,564,098 thousand during the six months ended June 30, 2021. At the end of the second quarter of the fiscal year under review, capital stock was ¥9,000,635 thousand and legal capital surplus was ¥8,993,023 thousand.

(Segment information, etc.)

[Segment information]

I. For six months ended June 30, 2020

As described in "For the six months ended June 30, 2021 (Matters related to changes, etc. in reportable segments)."

II. For six months ended June 30, 2021

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

(Matters related to changes, etc. in reportable segments)

The Company was previously composed of two reportable segments classified as the "pharmaceutical business" and the "diagnostic business." However, since more than 99% of net sales of the Company are from the pharmaceutical business and the trend is expected to continue, the Company changed the method of performance management and changed to a single segment of the "drug discovery business" from the first quarter of the fiscal year under review.

Since the Company now operates as a single segment due to the change explained above, the segment information for the six months ended June 30, 2020 and for the six months ended June 30, 2021 is omitted from this report.

3. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the six months ended June 30, 2021 totaled ¥321,294 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 June 30, 2021, 13 persons belonged to research and development department, equivalent to 36.1% 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 concluded agreements for exclusive licensing in Japan and Taiwan of Telomelysin and exclusive option right concerning the worldwide license for of Telomelysin, excluding Japan, Taiwan, China, Hong Kong and Macau, with Chugai in April 2019. If Chugai exercises the exclusive option right, the total amount the Company receives from Chugai under the agreement will be over ¥50 billion yen, and the Company has already received a contractual lump-sum payment and the first milestone revenue payment from Chugai under these agreements. Chugai has announced that as of July 26, 2021, application for approval for Telomelysin is planned in 2024, and the Company is now working with Chugai to push ahead with activities toward its launch.

The Company is also actively seeking new partners for licensing agreements in China, Hong Kong, and Macau, where a majority of the world's esophageal cancer patients are found.

In the U.S., the development of Telomelysin for esophageal cancer was designated as an orphan drug by the U.S. Food and Drug Administration (FDA) in June 2020. This designation entitles the Company to receiving from FDA advice and consultation for the development of Telomelysin, as well as receiving preferential treatment such as subsidies and tax deduction of clinical trial expenses. Furthermore, the drug will be given prior patent protection in the U.S. for seven years after the approval of Telomelysin, which ensures market exclusivity for this period. Along with the "SAKIGAKE Designation System" which designated the drug in April 2019, the Company plans to leverage such systems to develop Telomelysin for the treatment of esophageal cancer.

In February 2021, the World Health Organization (WHO) selected suratadenoturev as the International Nonproprietary Name (INN) for Telomelysin. Selection of the INN by WHO is an important step towards obtaining approval of a new drug. After the approval, the name will be used across the world.

As of June 30, 2021, Chugai, the licensee, is conducting the following four clinical trials in Japan:

i) Phase II clinical trial in combination with radiation therapy for esophageal cancer;
ii) Phase I clinical trial in combination with chemoradiotherapy for esophageal cancer;
iii) Phase I clinical trial in combination with atezolizumab, an anti-PD-L1 antibody, and bevacizumab, a molecular targeting drug, for hepatocellular cancer; and
iv) Phase I clinical trial in combination with atezolizumab, an anti-PD-L1 antibody, and chemoradiotherapy for head and neck cancer.

Regarding the above i) "Phase II clinical trial in combination with radiation therapy for esophageal cancer," administration by licensee Chugai to the first patient began in Japan in March 2020. The targeted number of patients to be administered is 37 for esophageal cancer patients refractory to resection through surgery and definitive chemoradiotherapy.

Regarding the above ii) "Phase I clinical trial in combination with chemoradiotherapy for esophageal cancer," licensee Chugai has been preparing to start the clinical trial for locally advanced esophageal cancer patients and started patient recruitment. The targeted number of patients is 20, and the trial is intended to evaluate primarily safety and secondarily efficacy.

Regarding the above iii) "Phase I clinical trial in combination with atezolizumab, an anti-PD-L1 antibody, and bevacizumab, a molecular targeting drug, for hepatocellular cancer," administration is in progress by Chugai. The trial is the first clinical trial where Telomelysin is administered in combination with atezolizumab, an anti-PD-L1 antibody, and administration to the first patient began in January 2021. The targeted number of patients is 20, and the trial is intended to evaluate primarily safety and secondarily efficacy.

Regarding the above iv) "Phase I clinical trial in combination with atezolizumab, an anti-PD-L1 antibody, and chemoradiotherapy for head and neck cancer," Chugai has been preparing to start clinical trial for locally advanced head and neck cancer patients and planned patient recruitment. The targeted number of patients is 23, and the trial is intended to evaluate primarily safety of administering Telomelysin in combination with atezolizumab, an anti-PD-L1 antibody, and chemoradiotherapy and secondarily efficacy.

In addition, the Company is conducting the following four clinical trials in Japan and overseas:

v) Phase II investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for gastric cancer/gastroesophageal junction cancer;
vi) Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer;
vii) Phase II investigator-initiated clinical trial in combination with radiation therapy and pembrolizumab, an anti-PD-1 antibody, for head and neck cancer; and
viii) Phase I investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for solid tumors.

Regarding the above v)" 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 in the U.S. 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 highly likely that this is the effect of administering Telomelysin. 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 vi) "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. The Company aims to enroll a maximum of 21 patients and begin administration to the first patient by the end of 2021. Telomelysin has been designated as an orphan drug in the U.S. as stated above, and this clinical trial will be conducted on that basis.

Regarding the above vii), "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 in 2022 and decide whether to continue with the clinical trial.

Regarding the above viii) "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 clinical trial where Telomelysin was administered to the primary tumor of esophagus, the safety of Telomelysin in combination with pembrolizumab, an anti-PD-1 antibody, and efficacy for some of the patients were shown. In the Phase Ib clinical trial currently in progress, 11 patients have been enrolled and followed up. The Company aims to compile data with a view to presenting them at academic conferences and other opportunities.

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 with a research group led by Director Masanori Baba of the Joint Research Center for Human Retrovirus Infection at Kagoshima University Campus. As a result, OBP-2001 was identified as a chemical compound fairly effective in suppressing the growth of SARS-CoV-2, which is the virus that causes

COVID-19. Furthermore, a comparative experiment in a same experimental system confirmed that the identified compound indicates activity equivalent to or higher than remdesivir (Gilead Sciences, Inc.), an approved treatment for COVID-19. In addition, the findings pointed to mechanisms different from those of remdesivir.

The Company then synthesized new chemical compounds in the joint research with Kagoshima University and identified OBP-2011 among them, which indicated higher activity. Based on the results of pre-clinical trials, it has been confirmed that this chemical compound can be orally administered. In addition, no abnormalities were observed in exploratory toxicity trials and exploratory genetic toxicity trials. It has also been confirmed in in vitro experiment that the chemical compound indicates as much activity for the UK and Brazilian variants of coronavirus, which may be resistant to vaccines, as it does for the wild type. 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.

Although attempts to contain the pandemic by vaccination are under way, the emergence of variants and issues regarding inoculation rates suggest that it is not easy to rein in the global pandemic only by vaccination. In addition, the world of the 21st century has already seen three coronavirus pandemics (SARS, MERS, COVID-19), and more pandemics are anticipated in the future. The Company aims to establish POC in the clinical trial targeting early-stage patients and to develop a therapeutic drug that turns patients SARS-CoV-2 negative in a short period of time and can be orally administered, with an eye on applying by the end of 2022 to conduct clinical trials.

3) 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). The Company positions OBP-702 as the “next generation Telomelysin” to follow Telomelysin itself, which has already been licensed to Chugai. In addition, a research group led by Professor Fujiwara 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) in April 2017 and March 2020, reporting on results of those trials at several conferences. The Company had originally planned to submit investigational new drug (IND) application for OBP-702 in 2022, but since the validation for GMP manufacturing is taking more time than expected, it now aims for IND submission in the U.S. in 2023.

4) 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 blood. By making use of AI technology, the Company aims to not only reduce the time for processing test results but also improve the sensitivity of CTC image analysis and the accuracy of the tests.

In terms of clinical research, an investigator-initiated clinical research in the field of lung cancer with the Department of Respiratory Medicine, Juntendo University, began in February 2020. Liquid Biotech USA, Inc., with which the Company has a licensing agreement for North America, is conducting joint research activities with research institutions in the U.S. for applications in the fields of lung cancer and female-specific cancer. When the platform under development at Juntendo University is completed, it will be brought into use to drive the diagnostic business.

5) 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, Bristol-Myers Squibb Co. (hereinafter “BMS”) 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. The Company has since concluded a new license agreement with Transposon Therapeutics, Inc. (the U.S.; hereinafter “Transposon”) totaling over $300 million. Transposon achieved its first milestone in November 2020.

Going forward, the Company will continuously monitor the progress of the development of OBP-601 by Transposon with a prospect for the clinical trials for intractable neurological diseases to start in 2021.

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, study enrollment of new patients has been tentatively suspended and the Company is considering the possibility of restarting with

another protocol including combinations with other drugs. Furthermore, the Company is exploring its potential use in the ophthalmic field, which is a new area of indication for OBP-801, and the outcome of a study by the Kyoto Prefectural University of Medicine was presented at the World Glaucoma Congress in June 2021.

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 (Chugai)
	Esophageal cancer	Chemoradiotherapy	Japan	Phase I (Chugai)
			U.S.	Phase I
	Hepatocellular cancer (HCC)	Anti-PD-L1 antibody atezolizumab Molecular targeting drug	Japan	Phase I (Chugai)
		-	South Korea and Taiwan	Phase I (complete)
	Head and neck cancer	Anti-PD-L1 antibody atezolizumab Chemoradiotherapy	Japan	Phase I (Chugai)
		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
OBP-2011	Novel coronavirus infection (COVID-19)	-	Worldwide	Pre-clinical
OBP-702	Solid tumor	Anti-PD-(L)1 antibody (expected)	U.S./Japan	Pre-clinical
OBP-601 (Censavudine)	Neurodegenerative diseases	TBD	U.S.	Phase I (in preparation)
	HIV infection	-	Europe, the U.S. and others	Phase IIb (complete)
OBP-801	Solid tumor	Anti-PD-(L)1 antibody (expected)	U.S.	Phase I
	Ophthalmic field	-	Japan	Pre-clinical
TelomeScan (OBP-401)	Solid tumor	-	Japan	Clinical research