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, 2021 [Japanese GAAP]

May 7, 2021

Company name: Oncolys BioPharma Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4588
URL: http://www.oncolys.com
Representative: Yasuo Urata, President & CEO
Contact: Keiji Yoshimura, Vice President & Accounting
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Scheduled date of filing quarterly securities report: May 7, 2021
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, 2021 (January 1, 2021 to March 31, 2021)

(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, 2021	62	(10.9)	(349)	-	(349)	-	(350)	-
March 31, 2020	70	45.2	(287)	-	(285)	-	(286)	-

	Basic earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
March 31, 2021	(22.36)	-
March 31, 2020	(19.96)	-

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of March 31, 2021	5,463	4,768	87.1
As of December 31, 2020	2,796	2,003	71.4

(Reference) Equity: As of March 31, 2021: ¥4,761 million
As of December 31, 2020: ¥1,995 million

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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	-				
Fiscal year ending December 31, 2021 (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, 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
Fiscal 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, 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):
March 31, 2021: 17,328,600 shares
December 31, 2020: 14,641,900 shares

2) Total number of treasury shares at the end of the period:
March 31, 2021: 19,462 shares
December 31, 2020: 14,462 shares

3) Average number of shares during the period:
Three months ended March 31, 2021: 15,677,731 shares
Three months ended March 31, 2020: 14,330,099 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

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(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 three months ended March 31, 2021 saw the government declare a state of emergency again due to the spread of COVID-19, which has left a significant impact on economic activities. While the Nikkei Stock Average exceeded the ¥30 thousand mark for the first time in approximately 30 years, the outlook is expected to remain uncertain.

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 three months ended March 31, 2021, Chugai Pharmaceutical Co., Ltd. (hereinafter "Chugai"), the licensee, began administration of Telomelysin virotherapy for cancer to the first patient in the clinical trial for hepatocellular cancer, following the trial for esophageal cancer. Furthermore, Chugai has started recruiting patients for the clinical trial in combination with chemoradiotherapy for esophageal cancer. With regards to clinical trials in the U.S. led by the Company, patient recruitment has started for the clinical trial in combination with chemoradiotherapy for esophageal cancer and the clinical trial for head and neck cancer, and administration to the first patient is expected to take place in the first half of 2021. For OBP-2011 for the treatment of COVID-19, the Company decided to commission GMP manufacturing of active pharmaceutical ingredients for investigational drugs to Iwaki Seiyaku and promoted activities with a view to applying in 2022 to conduct clinical trials. The Company also promoted clinical research with Juntendo University for TelomeScan, a cancer detection drug.

As a result, for the three months ended March 31, 2021, net sales were ¥62,603 thousand (net sales of ¥70,274 thousand in the same period of the previous year), and operating loss was ¥349,453 thousand (operating loss of ¥287,690 thousand in the same period of the previous year). In addition, the Company recorded interest income of ¥131 thousand, foreign exchange gains of ¥25,702 thousand, and other items as non-operating income and interest expenses of ¥932 thousand, amortization of restricted stock remuneration of ¥14,220 thousand, share issuance costs of ¥10,905 thousand, and other items as non-operating expenses. As a result, ordinary loss was ¥349,626 thousand (ordinary loss of ¥285,059 thousand in the same period of the previous year), and loss was ¥350,567 thousand (loss of ¥286,022 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 ¥5,463,183 thousand (95.4% increase compared with the end of the previous fiscal year), owing partly to an increase in cash and deposits. Specifically, the increase was mainly due to financing through issuance and exercise of share acquisition rights to develop a commercially viable manufacturing method for Telomelysin and for research and development expenses for next generation Telomelysin OBP-702 and OBP-2011, as well as through taking out long-term loans from Kobe Shinkin Bank. Liabilities were ¥694,343 thousand (12.5% decrease compared with the end of the previous fiscal year), owing partly to repayment of accounts payable - other. Net assets were ¥4,768,839

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thousand (138.0% 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 forecast are based on assumed rates of ¥105 per U.S. dollar and ¥125 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, novel coronavirus infection drugs, 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).

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2. Quarterly Financial Statements and Primary Notes
(1) Quarterly Balance Sheets

(Thousand yen)

	As of December 31, 2020	As of March 31, 2021
Assets		
Current assets		
Cash and deposits	2,067,927	4,979,253
Accounts receivable – trade	70,598	64,313
Finished goods	8,434	8,434
Supplies	2,038	4,361
Advance payments – other	43,354	43,492
Prepaid expenses	241,379	129,995
Accounts receivable – other	1,544	993
Consumption taxes receivable	95,445	6,453
Advances paid	14,935	1,702
Other	16	30
Total current assets	2,545,676	5,239,030
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	83,328
Accumulated depreciation	(66,207)	(62,671)
Tools, furniture and fixtures, net	21,317	20,657
Total property, plant and equipment	21,317	20,657
Intangible assets		
Software	650	600
Total intangible assets	650	600
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	33,213
Lease and guarantee deposits	21,229	21,229
Long-term prepaid expenses	63,996	36,418
Other	19	19
Total investments and other assets	228,769	202,895
Total non-current assets	250,736	224,152
Total assets	2,796,413	5,463,183

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(Thousand yen)

	As of December 31, 2020	As of March 31, 2021
Liabilities		
Current liabilities		
Short-term loans payable	150,008	183,344
Lease obligations	2,144	2,007
Accounts payable – other	206,610	54,819
Accrued expenses	15,333	12,229
Income taxes payable	33,486	24,391
Deposits received	7,661	6,702
Total current liabilities	415,244	283,494
Non-current liabilities		
Long-term loans payable	366,648	399,976
Lease obligations	6,275	5,769
Provision for retirement benefits	4,920	5,103
Total non-current liabilities	377,843	410,848
Total liabilities	793,087	694,343
Net assets		
Shareholders' equity		
Capital stock	7,436,537	8,994,485
Capital surplus		
Legal capital surplus	7,428,925	8,986,873
Other capital surplus	31,740	31,740
Total capital surpluses	7,460,666	9,018,614
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(12,901,296)	(13,251,864)
Total retained earnings	(12,901,296)	(13,251,864)
Treasury shares	(76)	(76)
Total shareholders' equity	1,995,830	4,761,159
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	4,768,839
Total liabilities and net assets	2,796,413	5,463,183

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(2) Quarterly Statements of Income

Three Months Ended March 31

(Thousand yen)

	For the three months ended March 31, 2020	For the three months ended March 31, 2021
Net sales	70,274	62,603
Cost of sales	19,506	35,427
Gross profit	50,768	27,175
Selling, general and administrative expenses	338,458	376,629
Operating loss	(287,690)	(349,453)
Non-operating income		
Interest income	5,107	131
Foreign exchange gains	-	25,702
Other	-	682
Total non-operating income	5,107	26,516
Non-operating expenses		
Interest expenses	776	932
Amortization of restricted stock remuneration	-	14,220
Share acquisition rights issuance costs	-	413
Share issuance costs	-	10,905
Foreign exchange losses	1,669	-
Other	30	217
Total non-operating expenses	2,476	26,689
Ordinary loss	(285,059)	(349,626)
Loss before income taxes	(285,059)	(349,626)
Income taxes - current	962	941
Total income taxes	962	941
Loss	(286,022)	(350,567)

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(3) Notes to Quarterly Financial Statements

(Notes on going concern assumption)

There is no relevant information.

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

The Company received payment for the exercise of stock acquisition rights during the period from January 5, 2021 to March 24, 2021. As a result, capital stock and legal capital surplus each increased by ¥1,557,948 thousand during the three months ended March 31, 2021. At the end of the first quarter of the fiscal year under review, capital stock was ¥8,994,485 thousand and legal capital surplus was ¥8,986,873 thousand.

(Segment information, etc.)

[Segment information]

I. For three months ended March 31, 2020

As described in "For three months ended March 31, 2021 (Matters related to changes, etc. in reportable segments)."

II. For three months ended March 31, 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.

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3. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the three months ended March 31, 2021 totaled ¥106,628 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, 2021, 15 persons belonged to research and development department, equivalent to 40.5% of the total number of employees.

(2) Research and development and business activities

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

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

The Company concluded exclusive licensing in Japan and Taiwan of Telomelysin and exclusive option right concerning the worldwide of Telomelysin, excluding Japan, Taiwan, China, Hong Kong and Macau with Chugai in April 2019. In case Chugai exercises the exclusive option right, the total amount of the license agreement the Company receives from Chugai could be over ¥50 billion, and the Company has already received a contractual lump-sum payment and the first milestone revenue payment from Chugai under these agreements. With regard to the development in Japan, Chugai has announced that as of April 22, 2021, application for approval for Telomelysin is planned in or after 2024.

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 enables FDA to provide advice and consultation for the development of Telomelysin, as well as receiving preferential treatment such as payment of 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 March 31, 2021, a total of eight clinical trials are simultaneously in progress. By licensee Chugai, 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 are being conducted in Japan.

In addition, the Company has been conducting in the U.S. 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 in Japan viii) Phase I investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for solid tumors.

<Development of Telomelysin by Chugai>

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,

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and bevacizumab, a molecular targeting drug, for hepatocellular cancer," administration is in progress by Chugai to evaluate the safety, tolerability, and secondarily efficacy. 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.

<Development of Telomelysin by the Company>

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 at 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 evaluate the progress of 18 patients by the first half 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. Despite the delay due to the spread of COVID-19, the Company aims to enroll a maximum of 21 patients and begin administration to the first patient in the first half 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," the preparation for beginning administration was completed in 2020, led by Cornell University in the U.S., and administration to the first patient is expected to begin in the first half of 2021. 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. The Phase Ib clinical trial currently in progress will be completed with the enrollment of 11 among the targeted 13 patients. The Company aims to compile intermediate data in 2021.

Telomelysin has been recognized as a designated product under the SAKIGAKE Designation System in Japan for esophageal cancer, as well as an orphan drug for esophageal cancer in the U.S. While the Company agreed with Jiangsu Hengrui Medicine Co., Ltd. to cancel the license agreement on the research, development, manufacturing, and sales rights in China, Hong Kong, and Macau in June 2020, going forward, the Company will accelerate activities to sign a new Telomelysin license agreement in countries and regions including the China area, which has the majority of the world's esophageal cancer patients.

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

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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 Brazilian and London variants of coronavirus, which may be resistant to vaccines, as it does for the wild type.

As an attempt to contain the pandemic by vaccination, multiple vaccines have already been approved and become viable in Europe and the U.S., and vaccine inoculation has started in Japan as well. Meanwhile, insufficient efficacy against variants and low vaccination 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 it is projected that pandemics are likely to keep occurring every few years. The Company aims to develop a therapeutic drug for PCR-positive patients that turns them 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 plans to proceed with GMP manufacturing and pre-clinical trials and engage in development in the U.S. for cancer associated with p53 gene deletion and mutation, as well as for cancer refractory to Telomelysin (OBP-301).

4) Activities related to TelomeScan (OBP-401), a cancer detection drug

Regarding TelomeScan, the Company concluded a development commission agreement for automated analysis software for Circulating Tumor Cell (CTC) with K.K. CYBO (hereinafter “CYBO”) in 2020, with the aim of automating the detection of CTC within blood. By utilizing CYBO’s AI technologies and developing the TelomeScan CTC Analysis System (T-CAS), software tailored for TelomeScan, the Company hopes to automate the detection of CTC, accelerate detection processing, and standardize detection results. Going forward, the Company aims to develop an improved version of the software, which not only detects CTC but also serves other purposes such as assessing the degree of malignancy of detected CTC.

In addition, ongoing research projects, despite the delay due to the COVID-19 pandemic, include an investigator-initiated clinical research in the field of lung cancer with the Department of Respiratory Medicine, Juntendo University, as well as joint research activities by the North American territory licensee Liquid Biotech USA, Inc. (hereinafter “Liquid”) with research institutions in the U.S for applications in the fields of lung cancer and female-specific cancer. Liquid will conduct the validation of T-CAS by using AI.

The Company will work on the construction of a platform for TelomeScan by using T-CAS, with a vision to upgrade the precision of its testing system to provide treatment options for patients.

5) Activities related to OBP-601 (Censavudine), a nucleoside reverse transcriptase inhibitor

The Company licensed in OBP-601 (Censavudine) from Yale University in 2006 and licensed it to Bristol-Myers Squibb Co. (hereinafter “BMS”) in 2010. From 2010 to 2014, BMS worked on its development up to the completion of Phase II clinical trials as a treatment drug for HIV infection. The license agreement, however, was terminated in 2014 due to changes in BMS’s business strategy. Since then, the Company actively worked on business activities to conclude new license agreements for OBP-601 in fields other than the infection field, and a research conducted by Brown University in the U.S., which studies neuropathology, suggested the possibility that OBP-601 inhibits reverse transcription and copying of retrotransposon. In June 2020, the Company concluded a new license agreement with Transposon Therapeutics, Inc. (the U.S.; hereinafter “Transposon”) totaling over $300 million. Furthermore, Transposon achieved its first milestone in November 2020.

As OBP-601 shows high intracerebral migration and clinical data for long-term administration is already

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available, Transposon's development of the drug may enjoy significant shortening or reduction of clinical and pre-clinical trials for confirming safety. In addition, Transposon completed Pre-IND with FDA in 2020 and has been preparing for the investigational new drug (IND) application to conduct clinical trials. Going forward, the Company will continuously monitor the progress of the development of OBP-601 by Transposon in the hope that the start of clinical trials for intractable neurological diseases will be approved by FDA 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 the potential use in the ophthalmic field, which is a new area of indication for OBP-801.

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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
TelomeScan (OBP-401)	Solid tumor	—	Japan	Clinical research

TRANSLATION