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, 2020 [Japanese GAAP]

August 7, 2020

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: August 7, 2020
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, 2020 (January 1, 2020 to June 30, 2020)

(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, 2020	136	(78.1)	(660)	-	(662)	-	(664)	-
June 30, 2019	621	586.6	(275)	-	(271)	-	(273)	-

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
June 30, 2020	(46.43)	-
June 30, 2019	(20.07)	-

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of June 30, 2020	3,519	2,795	79.2
As of December 31, 2019	4,380	3,454	78.7

(Reference) Equity: As of June 30, 2020: ¥2,787 million
As of December 31, 2019: ¥3,446 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, 2019	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2020	-	0.00			
Fiscal year ending December 31, 2020 (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, 2020 (January 1, 2020 to December 31, 2020)

Given that there are currently many indeterminate factors that may influence financial results, the Company believes that it is unrealistic to attempt to calculate appropriate and realistic numerical values for the financial results forecast and therefore has not disclosed any forecasts for financial results.

*** 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, 2020: 14,347,300 shares
December 31, 2019: 14,331,300 shares

2) Total number of treasury shares at the end of the period:
June 30, 2020: 21,631 shares
December 31, 2019: 15,000 shares

3) Average number of shares during the period:
Six months ended June 30, 2020: 14,316,246 shares
Six months ended June 30, 2019: 13,624,853 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 Japanese economy during the six months ended June 30, 2020 saw a significant decline in trade-related businesses, as well as decreasing inbound demand from foreign visitors to Japan and household consumption activities, due to the continued impact of coronavirus disease (COVID-19). In addition, prospects remain uncertain due to concerns over the second and third waves of the pandemic, and it is expected to take some time before the situation takes a turn for the better and COVID-19 is completely contained.

Amid these circumstances, the Company endeavored to increase management efficiency and actively expanded its research, development and licensing activities. For the purpose of accelerating research and development in the pharmaceutical business, the Company has established OPA Therapeutics Inc. (hereinafter "OPA"), a wholly-owned subsidiary of the Company in April 2020. OPA has its business location in the state of California, the U.S., and will primarily undertake the execution of non-clinical trials for various pipelines. Dr. Frank Tufaro (former Chief Executive Officer of DNAtrix Inc.) who has over 20 years of experience in oncolytic virus research and development, was appointed as President of OPA.

In the pharmaceutical business, the Company promoted research, development, and licensing activities centered on Telomelysin (OBP-301) virotherapy for cancer and OBP-601 nucleoside reverse transcriptase inhibitor (Censavudine). In addition, in the diagnostic business, the Company promoted research and development activities centered on TelomeScan (OBP-401). For details of the Company's activities, please refer to "3. Supplemental Information (1) Research and development activities."

As a result, for the six months ended June 30, 2020, net sales were ¥136,115 thousand (net sales of ¥621,006 thousand in the same period of the previous year), and operating loss was ¥660,290 thousand (operating loss of ¥275,221 thousand in the same period of the previous year). In addition, the Company recorded interest income of ¥10,047 thousand as non-operating income and interest expenses of ¥2,001 thousand, amortization of restricted stock remuneration of ¥6,055 thousand, foreign exchange losses of ¥4,561 thousand, and other items as non-operating expenses. As a result, ordinary loss was ¥662,891 thousand (ordinary loss of ¥271,629 thousand in the same period of the previous year), and loss was ¥664,734 thousand (loss of ¥273,478 thousand in the same period of the previous year).

Financial results by segment were as follows.

1) Pharmaceutical business

In the pharmaceutical business, the Company recorded contractual lump-sum revenue payments received following the execution of a new license agreement for OBP-601 with Transposon Therapeutics, Inc. (hereinafter "Transposon"), joint development revenue from Medigen Biotechnology Corp. (Taiwan; hereinafter "Medigen") for Telomelysin, and business contract revenue from Okayama University for next generation Telomelysin OBP-702, among others. As a result, net sales were ¥135,710 thousand (net sales of ¥616,525 thousand in the same period of the previous year) and operating loss was ¥291,827 thousand (operating profit of ¥169,853 thousand in the same period of the previous year).

2) Diagnostic business

In the diagnostic business, the Company promoted the clinical research with Juntendo University to consider prognosis prediction of treatment for circulating tumor cell (CTC) for patients with lung cancer. As a result, net sales were ¥405 thousand (net sales of ¥4,481 thousand in the same period of the previous year) and operating loss was ¥22,978 thousand (operating loss of ¥128,723 thousand in the same period of the previous year).

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(2) Explanation of Financial Position

Assets at the end of the second quarter of the fiscal year under review were ¥3,519,897 thousand (19.6% decline compared with the end of the previous fiscal year), owing partly to a decline in cash and deposits.

Liabilities were ¥724,809 thousand (21.7% decline compared with the end of the previous fiscal year), owing partly to a decline in accounts payable - other. Net assets were ¥2,795,087 thousand (19.1% decline compared with the end of the previous fiscal year), owing to loss incurred and other factors. Additionally, treasury shares of ¥41 thousand acquired through purchase demands from shareholders holding less than one unit were recorded in net assets.

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

Focusing on furthering the development of Telomelysin, the Company actively promotes clinical trials, non-clinical trials, and the manufacture of investigational new drugs for various domestic and international pipelines in order to further improve corporate value and is strengthening efforts to sign license agreements with major pharmaceutical companies both in Japan and overseas. Meanwhile, the Company's base of stable revenue is still small, and financial results fluctuate widely due to factors including contractual lump-sum revenue payments on the signing of new license agreements and development milestone revenue payments generated by events and achievements of partners with license agreements.

Given that there are currently many indeterminate factors that may influence financial results, the Company believes that it is unrealistic to attempt to calculate appropriate and realistic numerical values for the financial results forecast and therefore has not disclosed any forecasts for financial results.

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2. Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousand yen)

	As of December 31, 2019	As of June 30, 2020
Assets		
Current assets		
Cash and deposits	3,342,585	2,607,198
Accounts receivable – trade	169,308	66,570
Finished goods	8,504	8,434
Work in process	3,898	—
Supplies	2,515	1,656
Advance payments – other	47,737	46,704
Prepaid expenses	202,709	180,080
Short-term loans receivable from subsidiaries and associates	10,954	10,771
Accounts receivable – other	37,069	46,281
Consumption taxes receivable	—	37,560
Other	1,146	65
Total current assets	3,826,429	3,005,324
Non-current assets		
Property, plant and equipment		
Buildings	2,794	2,794
Accumulated depreciation	(2,794)	(2,794)
Buildings, net	—	—
Tools, furniture and fixtures	73,673	75,876
Accumulated depreciation	(61,849)	(63,806)
Tools, furniture and fixtures, net	11,823	12,070
Total property, plant and equipment	11,823	12,070
Intangible assets		
Software	850	750
Total intangible assets	850	750
Investments and other assets		
Investment securities	329,333	323,588
Shares of subsidiaries and associates	101,153	111,916
Investments in capital	100	100
Long-term loans receivable from subsidiaries and associates	—	21,542
Lease and guarantee deposits	27,532	29,526
Long-term prepaid expenses	82,816	15,060
Other	19	19
Total investments and other assets	540,953	501,752
Total non-current assets	553,626	514,572
Total assets	4,380,056	3,519,897

(Thousand yen)

	As of December 31, 2019	As of June 30, 2020
Liabilities		
Current liabilities		
Short-term loans payable	127,776	150,008
Lease obligations	3,147	2,561
Accounts payable – other	253,275	96,561
Accrued expenses	12,338	10,895
Income taxes payable	43,859	38,989
Accrued consumption taxes	75,828	—
Deposits received	7,576	5,584
Total current liabilities	523,801	304,601
Non-current liabilities		
Long-term loans payable	388,880	408,318
Lease obligations	8,419	7,279
Provision for retirement benefits	4,906	4,611
Total non-current liabilities	402,205	420,208
Total liabilities	926,007	724,809
Net assets		
Shareholders' equity		
Capital stock	7,121,273	7,126,603
Deposits for subscriptions of shares	—	1,000
Capital surplus		
Legal capital surplus	7,113,773	7,119,103
Other capital surplus	9,650	9,650
Total capital surpluses	7,123,423	7,128,753
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(10,806,209)	(11,470,944)
Total retained earnings	(10,806,209)	(11,470,944)
Treasury shares	—	(41)
Total shareholders' equity	3,438,488	2,785,372
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	7,620	1,875
Total valuation and translation adjustments	7,620	1,875
Share acquisition rights	7,940	7,840
Total net assets	3,454,048	2,795,087
Total liabilities and net assets	4,380,056	3,519,897

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(2) Quarterly Statements of Income

Six Months Ended June 30

(Thousand yen)

	For the six months ended June 30, 2019	For the six months ended June 30, 2020
Net sales	621,006	136,115
Cost of sales	50,834	34,661
Gross profit	570,172	101,453
Selling, general and administrative expenses	845,393	761,744
Operating loss	(275,221)	(660,290)
Non-operating income		
Interest income	11,703	10,047
Dividend income	4	—
Other	77	—
Total non-operating income	11,784	10,047
Non-operating expenses		
Interest expenses	1,770	2,001
Amortization of restricted stock remuneration	—	6,055
Foreign exchange losses	6,421	4,561
Other	—	30
Total non-operating expenses	8,192	12,648
Ordinary loss	(271,629)	(662,891)
Loss before income taxes	(271,629)	(662,891)
Income taxes - current	1,848	1,843
Total income taxes	1,848	1,843
Loss	(273,478)	(664,734)

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(3) Quarterly Statements of Cash Flows

(Thousand yen)

	For the six months ended June 30, 2019	For the six months ended June 30, 2020
Cash flows from operating activities		
Loss before income taxes	(271,629)	(662,891)
Depreciation	1,155	2,056
Share-based remuneration expenses	26,861	93,185
Increase (decrease) in provision for retirement benefits	442	(295)
Interest and dividend income	(11,707)	(10,047)
Interest expenses	1,770	2,001
Foreign exchange losses (gains)	4,861	3,835
Decrease (increase) in notes and accounts receivable - trade	31,921	102,738
Decrease (increase) in inventories	554	4,827
Decrease (increase) in prepaid expenses	1,164	(8,852)
Decrease (increase) in accounts receivable - other	320	—
Increase (decrease) in accrued consumption taxes	—	(75,828)
Decrease (increase) in advance payments - other	2,140	1,032
Increase (decrease) in accounts payable - other	(32,757)	(157,266)
Other, net	52,103	(42,453)
Subtotal	(192,800)	(741,903)
Interest and dividend income received	1,165	836
Interest expenses paid	(1,772)	(2,430)
Income taxes paid	(3,723)	(3,718)
Net cash provided by (used in) operating activities	(197,130)	(747,216)
Cash flows from investing activities		
Purchase of property, plant and equipment	(2,877)	(1,225)
Payments for investments in capital of subsidiaries and associates	—	(10,763)
Long-term loan advances	—	(21,762)
Payments for lease and guarantee deposits	(80)	(2,451)
Net cash provided by (used in) investing activities	(2,957)	(36,201)
Cash flows from financing activities		
Proceeds from long-term loans payable	200,000	100,000
Repayments of long-term loans payable	(27,780)	(58,330)
Repayments of lease obligations	(3,851)	(1,726)
Proceeds from issuance of common shares	943,348	10,560
Purchase of treasury shares of subsidiaries	—	1,000
Purchase of treasury shares	—	(41)
Net cash provided by (used in) financing activities	1,111,716	51,462
Effect of exchange rate change on cash and cash equivalents	(4,534)	(3,432)
Net increase (decrease) in cash and cash equivalents	907,093	(735,387)
Cash and cash equivalents at beginning of year	2,218,074	3,097,514
Cash and cash equivalents at end of period	3,125,167	2,362,127

(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)

There is no relevant information.

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(Segment information, etc.)

[Segment information]

I. For six months ended June 30, 2019

1. Information on net sales and profit (loss) by reportable segment

(Thousand yen)

	Reportable segment			Adjustment (Note 1)	Amount recorded in Quarterly Financial Statements (Note 2)
	Pharmaceutical Business	Diagnostic Business	Total		
Net sales					
Net sales to outside customers	616,525	4,481	621,006	—	621,006
Inter-segment net sales or transfers	—	—	—	—	—
Total	616,525	4,481	621,006	—	621,006
Segment profit (loss)	169,853	(128,723)	41,129	(316,351)	(275,221)

(Notes) 1. The adjustment to segment profit (loss) of negative ¥316,351 thousand is a corporate expense that has not been allocated to reportable segments, and is mainly expenses related to administrative departments that do not belong to any reportable segment.

2. Segment loss has been adjusted with operating loss in quarterly financial statements.

2. Information on impairment loss of non-current assets or goodwill, etc., for each reportable segment

There is no relevant information.

II. For six months ended June 30, 2020

1. Information on net sales and profit (loss) by reportable segment

(Thousand yen)

	Reportable segment			Adjustment (Note 1)	Amount recorded in Quarterly Financial Statements (Note 2)
	Pharmaceutical Business	Diagnostic Business	Total		
Net sales					
Net sales to outside customers	135,710	405	136,115	—	136,115
Inter-segment net sales or transfers	—	—	—	—	—
Total	135,710	405	136,115	—	136,115
Segment profit (loss)	(291,827)	(22,978)	(314,805)	(345,484)	(660,290)

(Notes) 1. The adjustment to segment profit (loss) of negative ¥345,484 thousand is a corporate expense that has not been allocated to reportable segments, and is mainly expenses related to administrative departments that do not belong to any reportable segment.

2. Segment loss has been adjusted with operating loss in quarterly financial statements.

2. Information on impairment loss of non-current assets or goodwill, etc., for each reportable segment

There is no relevant information.

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3. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the six months ended June 30, 2020 totaled ¥397,263 thousand, including ¥344,055 thousand for the pharmaceutical business, ¥14,754 thousand for the diagnostic business, and ¥38,453 thousand shared by both segments.

Furthermore, the status of research and development activities during the fiscal year under review is as follows.

(1) Research and development structure

As of June 30, 2020, 13 persons belonged to research and development department, equivalent to 38.2% 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.

(a) Pharmaceutical business

1) Activities related to Telomelysin (OBP-301) 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 Pharmaceutical Co., Ltd. (hereinafter "Chugai") in April 2019. In case Chugai exercises the exclusive option right, the total amount of the license agreement the Company receives from Chugai is 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.

In addition, in June 2020, the development of Telomelysin for esophageal cancer was designated as an orphan drug by the U.S. Food and Drug Administration (FDA). 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.

As of June 30, 2020, five clinical trials are simultaneously in progress for Telomelysin (OBP-301) virotherapy for cancer: i) Phase II clinical trial in combination with radiation therapy for esophageal cancer; ii) Phase I investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for solid tumors; 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 sponsor-initiated clinical trial for hepatocellular cancer; and v) Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer in the U.S.

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. According to Chugai's disclosure materials on July 27, 2020, Chugai plans to apply for approval for Telomelysin in 2022.

Regarding the above ii) Phase I investigator-initiated clinical trial in combination with an anti-PD-1 antibody for various types of solid tumors in the process of the development centered on esophageal cancer in combination with pembrolizumab, an anti-PD-1 antibody, administration to patients began in December 2017. The administration of Phase Ia clinical trials where Telomelysin was administered to the primary tumor of esophagus was completed, and it transitioned to a Phase Ib clinical trial where Telomelysin was administered to the liver metastasis site. 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, was shown, and it was reported that systemic partial responses (PR) were observed in 3 out of 9 patients. For the Phase Ib clinical trial currently in progress, enrollment of 9 among the targeted 13 patients was completed. After compiling intermediate data by the end of 2020, the possibility of transition to sponsor-initiated clinical trials will be considered.

Regarding the above iii) "Phase II investigator-initiated clinical trial in combination with pembrolizumab, an

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anti-PD-1 antibody for gastric cancer / gastroesophageal junction cancer" at Cornell University in the U.S., administration to the first patient began in May 2019. It will be administered to up to 37 patients, and an evaluation of the efficacy and safety of Telomelysin and pembrolizumab, an anti-PD-1 antibody, will be performed. The Company aims to make considerations based on a progress report on around 10 patients during 2020.

Regarding the above iv) Phase I sponsor-initiated clinical trial for hepatocellular cancer, administration of the final case was completed in April 2020 with Pusan National University (South Korea) and National Taiwan University (Taiwan) as trial sites. As a result, the evaluation of the safety of administering Telomelysin for hepatocellular cancer by the Data and Safety Monitoring Committee was completed, completing the Phase I sponsor-initiated clinical trial.

The Company will compile the data by the end of 2020, and plans to determine the future development of the drug for hepatocellular cancer upon discussion with Chugai, the licensee for Telomelysin.

Regarding the above v) Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer in the U.S., NRG Oncology, a leading cancer research group in the U.S., is leading the preparation for beginning administration. In addition, 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.

Furthermore, in the U.S., the Company is preparing for beginning Phase II investigator-initiated clinical trials combining radiation therapy and anti-PD-1 antibody for head and neck cancer.

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 license agreement in China, which has the majority of the world's esophageal cancer patients.

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

OBP-702, an oncolytic gene therapy, has two anti-tumor effects which combine the "gene therapy" of the p53 cancer suppressor gene 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 will proceed with GMP and non-clinical trials on OBP-702 and aims to begin clinical trials by 2022.

3) Activities related to OBP-601 (Censavudine)

The Company licensed in OBP-601, a nucleoside reverse transcriptase inhibitor, from Yale University in 2006. From 2010 to 2014, Bristol-Myers Squibb Co. promoted its development up to the completion of Phase II clinical trials as a treatment for HIV infection. Since then, the anti-HIV drug market has become saturated, and given the small possibility of new licensing for HIV indications, the Company actively worked on business activities to conclude new license agreements for OBP-601 in fields other than the infection field.

As a result, 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 totaling over $300 million.

As OBP-601 shows high intracerebral migration and clinical data for long-term administration is already available, Transposon's development of the drug may enjoy significant shortening or reduction of non-clinical trials, such as clinical trials for confirming safety.

Going forward, the Company will continuously monitor the progress of the development of OBP-601 by Transposon in the hope that it will become a groundbreaking treatment for neurodegenerative disorders.

4) 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

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another protocol including combinations with other drugs. Furthermore, the Company applied for a patent concerning the ophthalmic field as a new area of indication for OBP-801 in July 2018 with an ophthalmology research group from Kyoto Prefectural University of Medicine and is continuing to conduct joint research with them.

5) Activities related to OBP-AI-005, a COVID-19 treatment development project

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, Kagoshima University identified a group of chemical compounds that are highly effective in suppressing the growth of SARS-CoV-2, which is the virus that causes COVID-19. Furthermore, an experiment to simultaneously compare activity in the same system confirmed that the identified compounds indicate activity equivalent to or higher than remdesivir (Gilead Sciences, Inc.), an approved treatment for COVID-19.

Going forward, with regard to OBP-AI-005, a COVID-19 treatment development project, the Company will clarify its mechanism of action, develop a method for mass synthesis, and conduct pre-clinical trials including toxicity trials, in addition to conducting GMP manufacturing of investigational drugs, to prepare for the start of clinical trials.

The status of clinical trials in the Pharmaceutical Business is as follows.

Development code	Trademark or name	Indication	Development region	Development stage
OBP-301	Telomelysin (Virotherapy for cancer)	Esophageal cancer In combination with radiation therapy	Japan	Phase II
		Esophageal cancer (solid tumor) In combination with anti-PD-1 antibody	Japan	Phase I
		Esophageal cancer In combination with radiation therapy and chemotherapy	U.S.	Phase I
		Gastric / gastroesophageal junction cancer In combination with anti-PD-1 antibody	U.S.	Phase II
		Head and neck cancer In combination with radiation therapy and anti-PD-1 antibody	U.S.	Phase II (in preparation)
		HCC	South Korea and Taiwan	Phase I (complete)
OBP-801	HDAC inhibitor	Various types of solid tumor	U.S.	Phase I
OBP-601	Censavudine Nucleoside reverse transcriptase inhibitor	HIV infection	Europe, the U.S. and others	Phase IIb (complete)
		Neurodegenerative disorder, etc.	U.S.	Phase I / II (in preparation)

(b) Diagnostic business

Regarding TelomeScan, a cancer detection drug, the Company concluded a development commission agreement for automated cell analysis software with K.K. CYBO (hereinafter “CYBO”) with the aim of automating the detection of CTC within blood. By developing software tailored for TelomeScan utilizing CYBO’s AI technologies, the Company hopes to automate the detection of CTC, accelerate detection processing, and standardize detection results.

In addition, an investor-initiated clinical research is underway for CTC in the field of lung cancer with Juntendo University. For applications in the field of female-specific cancer, the Company will launch a more accurate CTC testing system with detection for human papillomavirus genes from CTC of patients with cervical cancer. Liquid Biotech USA, Inc. (the U.S.), to which rights were granted in the North American territory, is proceeding with joint research activities with universities and research institutions in the U.S., and will establish a joint structure to acquire wider markets together with the Company.

In the future, the Company will enable not only detection of CTC by using TelomeScan but also gene testing for detected cells, with a vision to upgrade its testing system to provide treatment options for patients with cancer.

TRANSLATION