NB: this is a summary translation of the press release original drafted in Japanese for the disclosure required in compliance with the TSE regulations.

Non-consolidated Financial Results for the Nine Months Ended September 30, 2020 [Japanese GAAP]

November 6, 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
Contact: Keiji Yoshimura, Vice President & Management
Email: oncolys_information@oncolys.com
Scheduled date of filing quarterly securities report: November 6, 2020
Scheduled date of commencing dividend payments: —
Availability of supplementary briefing material on quarterly financial results: No
Schedule of quarterly financial results briefing session: No

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

1. Financial Results for the Nine Months Ended September 30, 2020 (January 1, 2020 to September 30, 2020)

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

	Net sales		Operating profit		Ordinary profit		Profit	
Nine months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
September 30, 2020	207	(67.5)	(1,167)	-	(1,185)	-	(1,545)	-
September 30, 2019	640	440.5	(586)	-	(587)	-	(590)	-

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2020	(107.64)	-
September 30, 2019	(42.73)	-

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of September 30, 2020	2,962	2,329	78.4
As of December 31, 2019	4,380	3,454	78.7

(Reference) Equity: As of September 30, 2020: ¥2,322 million
As of December 31, 2019: ¥3,446 million

TRANSLATION

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 financial results forecast, and therefore does not disclose any forecast of 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):
September 30, 2020: 14,471,300 shares
December 31, 2019: 14,331,300 shares

2) Total number of treasury shares at the end of the period:
September 30, 2020: 11,631 shares
December 31, 2019: 15,000 shares

3) Average number of shares during the period:
Nine months ended September 30, 2020: 14,356,563 shares
Nine months ended September 30, 2019: 13,820,591 shares

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

* Explanation of the proper use of financial results forecast and other notes

(Note regarding forward-looking statements, etc.)

The earnings forecasts and other forward-looking statements herein are based on information available to the Company at the time of the release of these materials and certain assumptions deemed reasonable, and do not represent a commitment from the Company that they will be achieved. In addition, actual financial results, etc. may differ significantly due to a wide range of factors. For the assumptions used in forecasting financial results and notes regarding the use of financial forecasts, etc., please see "1. Qualitative Information on Quarterly Financial Results for the Period under Review (3) Explanation of Financial Results Forecast and Other Forward-looking Information" on page 2 of the supplementary material.

TRANSLATION

Table of Contents

1. Qualitative Information on Quarterly Financial Results for the Period Under Review 2
(1) Explanation of Business Results 2
(2) Explanation of Financial Position 3
(3) Explanation of Financial Results Forecast and Other Forward-looking Information 3

2. Quarterly Financial Statements and Primary Notes 4
(1) Quarterly Balance Sheets 4
(2) Quarterly Statements of Income 6
Nine Months Ended September 30 6
(3) Notes to Quarterly Financial Statements 7
(Notes on going concern assumption) 7
(Notes in the case of significant changes in shareholders' equity) 7
(Segment information, etc.) 8

3. Supplemental Information 9
(1) Research and development activities 9

TRANSLATION

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

(1) Explanation of Business Results

For the Japanese economy during the nine months ended September 30, 2020, prospects remain uncertain as caution concerning the spread of coronavirus disease (COVID-19) stays elevated, despite government-led measures taken to stimulate stagnant economic activity due to COVID-19. Regarding the global economy, the real economy is also expected to shrink owing to the spread of COVID-19, US-China trade friction, etc.

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 be in charge of non-clinical trials for various pipelines and business associated with virus manufacturing. Dr. Frank Tufaro (former Chief Executive Officer of DNAtrix Inc.) who has over 30 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, OBP-601 nucleoside reverse transcriptase inhibitor (Censavudine), and OBP-2001 for COVID-19 treatment. 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 nine months ended September 30, 2020, net sales were ¥207,611 thousand (net sales of ¥640,111 thousand in the same period of the previous year), and operating loss was ¥1,167,504 thousand (operating loss of ¥586,988 thousand in the same period of the previous year). The Company recorded interest income of ¥485 thousand as non-operating income and interest expenses of ¥3,133 thousand, amortization of restricted stock remuneration of ¥6,342 thousand, foreign exchange losses of ¥9,412 thousand, and other items as non-operating expenses. As a result, ordinary loss was ¥1,185,938 thousand (ordinary loss of ¥587,805 thousand in the same period of the previous year). In addition, the Company recognized extraordinary losses of ¥356,681 due to impairment of investment securities of Unleash Immuno Oncolytics, Inc. As a result, loss was ¥1,545,408 thousand (loss of ¥590,619 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 ¥207,206 thousand (net sales of ¥635,629 thousand in the same period of the previous year) and operating loss was ¥496,471 thousand (operating profit of ¥74,010 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 ¥34,274 thousand (operating loss of ¥147,079 thousand in the same period of the previous year).

TRANSLATION

(2) Explanation of Financial Position

Status of Assets, Liabilities and Net Assets

Assets at the end of the third quarter of the fiscal year under review were ¥2,962,434 thousand (32.4% decrease compared with the end of the previous fiscal year), owing partly to a decrease in cash and deposits. Liabilities were ¥632,544 thousand (31.7% decrease compared with the end of the previous fiscal year), owing partly to repayment of accounts payable - other. Net assets were ¥2,329,890 thousand (32.5% decrease compared with the end of the previous fiscal year), owing to loss incurred and other factors.

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

The Company's base of stable revenue is still small, and financial results fluctuate widely due to 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.

TRANSLATION

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousand yen)

	As of December 31, 2019	As of September 30, 2020
Assets		
Current assets		
Cash and deposits	3,342,585	2,095,513
Accounts receivable – trade	169,308	116,394
Finished goods	8,504	8,434
Work in process	3,898	—
Supplies	2,515	1,921
Advance payments – other	47,737	46,704
Prepaid expenses	202,709	348,964
Short term loans receivable from subsidiaries and associates	10,954	
Accounts receivable – other	37,069	145
Consumption taxes receivable	—	60,339
Other	1,146	6,463
Total current assets	3,826,429	2,684,882
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	76,229
Accumulated depreciation	(61,849)	(64,983)
Tools, furniture and fixtures, net	11,823	11,246
Total property, plant and equipment	11,823	11,246
Intangible assets		
Software	850	700
Total intangible assets	850	700
Investments and other assets		
Investment securities	329,333	458
Shares of subsidiaries and associates	101,153	111,916
Investments in capital	100	100
Long-term loans receivable from subsidiaries and associates	—	31,734
Lease and guarantee deposits	27,532	29,193
Long-term prepaid expenses	82,816	92,184
Other	19	19
Total investments and other assets	540,953	265,605
Total non-current assets	553,626	277,551
Total assets	4,380,056	2,962,434

(Thousand yen)

	As of December 31, 2019	As of September 30, 2020
Liabilities		
Current liabilities		
Short-term loans payable	127,776	150,008
Lease obligations	3,147	2,353
Accounts payable – other	253,275	56,625
Accrued expenses	12,338	11,357
Income taxes payable	43,859	11,730
Accrued consumption taxes	75,828	—
Deposits received	7,576	5,603
Total current liabilities	523,801	237,679
Non-current liabilities		
Long-term loans payable	388,880	383,316
Lease obligations	8,419	6,779
Provision for retirement benefits	4,906	4,770
Total non-current liabilities	402,205	394,865
Total liabilities	926,007	632,544
Net assets		
Shareholders' equity		
Capital stock	7,121,273	7,324,914
Capital surplus		
Legal capital surplus	7,113,773	7,317,302
Other capital surplus	9,650	31,760
Total capital surpluses	7,123,423	7,349,062
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(10,806,209)	(12,351,617)
Total retained earnings	(10,806,209)	(12,351,617)
Treasury shares	—	(41)
Total shareholders' equity	3,438,488	2,322,318
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	7,620	(254)
Total valuation and translation adjustments	7,620	(254)
Share acquisition rights	7,940	7,826
Total net assets	3,454,048	2,329,890
Total liabilities and net assets	4,380,056	2,962,434

TRANSLATION

(2) Quarterly Statements of Income

Nine Months Ended September 30

(Thousand yen)

	For the nine months ended September 30, 2019	For the nine months ended September 30, 2020
Net sales	640,111	207,611
Cost of sales	59,111	74,309
Gross profit	580,999	133,302
Selling, general and administrative expenses	1,167,988	1,300,807
Operating loss	(586,988)	(1,167,504)
Non-operating income		
Interest income	17,648	485
Dividend income	4	—
Other	217	—
Total non-operating income	17,869	485
Non-operating expenses		
Interest expenses	2,821	3,133
Amortization of restricted stock remuneration	10,005	6,342
Foreign exchange losses	5,860	9,412
Other	—	30
Total non-operating expenses	18,686	18,918
Ordinary loss	(587,805)	(1,185,938)
Loss on valuation of investment securities	—	321,000
Bad debts expenses	—	35,681
Total extraordinary losses	—	356,681
Loss before income taxes	(587,805)	(1,542,619)
Income taxes - current	2,813	2,789
Total income taxes	2,813	2,789
Loss	(590,619)	(1,545,408)

TRANSLATION

(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)

With the receipt of payments for the exercise of stock acquisition rights during the period from March 11, 2020 to July 3, 2020, capital stock and legal capital surplus each increased by ¥11,225 thousand during the nine months ended September 30, 2020. In addition, pursuant to the resolution by the Board of Directors held on June 25, 2020, the Company issued new shares as restricted stock compensation on July 14, 2020, and capital stock and legal capital surplus increased by ¥192,416 thousand and ¥192,304 thousand, respectively.

As a result, at the end of the third quarter of the fiscal year under review, capital stock was ¥7,324,914 thousand and legal capital surplus was ¥7,317,302 thousand.

TRANSLATION

(Segment information, etc.)

[Segment information]

I. For nine months ended September 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	635,629	4,481	640,111	—	640,111
Inter-segment net sales or transfers	—	—	—	—	—
Total	635,629	4,481	640,111	—	640,111
Segment profit (loss)	74,010	(147,079)	(73,068)	(513,919)	(586,988)

(Notes) 1. The adjustment to segment profit (loss) of negative ¥513,919 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 nine months ended September 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	207,206	405	207,611	—	207,611
Inter-segment net sales or transfers	—	—	—	—	—
Total	207,206	405	207,611	—	207,611
Segment profit (loss)	(496,471)	(34,274)	(530,745)	(636,759)	(1,167,504)

(Notes) 1. The adjustment to segment profit (loss) of negative ¥636,759 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.

TRANSLATION

3. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the nine months ended September 30, 2020 totaled ¥647,030 thousand, including ¥563,601 thousand for the pharmaceutical business, ¥22,855 thousand for the diagnostic business, and ¥60,572 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 September 30, 2020, 14 persons belonged to research and development department, equivalent to 38.9% 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 September 30, 2020, multiple 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; v) Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer in the U.S.; and vi) Phase II investigator-initiated clinical trial in combination with radiation therapy and pembrolizumab, an anti-PD-1 antibody, for head and neck cancer in the U.S. In addition, as for the Phase I clinical trial in combination with chemoradiotherapy for esophageal cancer in Japan, Chugai has been preparing to start clinical trial. As per the development for Telomelysin of hepatocellular carcinoma treatment going forward will be decided in consultation with Chugai, which is the licensee of Telomelysin.

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 October 22, 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. 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 10 among the targeted 13 patients was completed. Going forward, we will finish compiling intermediate data by the end of 2020, and consider the possibility of transition to sponsor-initiated clinical trials.

TRANSLATION

Regarding the above iii) “Phase II investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody for gastric cancer / gastroesophageal junction cancer” 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.

Regarding the above vi) “Phase II investigator-initiated clinical trial in combination with radiation therapy and pembrolizumab, an anti-PD-1 antibody, for head and neck cancer in the U.S.,” Cornell University in the U.S. is leading the preparation for beginning administration. Head and neck cancer is a refractory tumor that can significantly reduce quality of life, and radiation therapy is the main treatment that is effective locally, other than surgical operations. In this clinical trial, we will examine 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 that have been observed so far.

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 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-2001 for COVID-19 treatment

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, a group of chemical compounds were identified that are highly 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 compounds indicate activity equivalent to or higher than remdesivir (Gilead Sciences, Inc.), an approved treatment for COVID-19.

The Company identified OBP-2001 in the group of compounds synthesized in the joint research with Kagoshima University and carried out exploratory toxicity trials. As a result, no changes were observed in general conditions, body weights, hematological/biochemical tests, and autopsy findings. In addition, the half-life in blood was estimated to be approximately five hours.

Based on these results, the Company aims to develop OBP-2001 into a formulation that specifically inhibits the growth of SARS-CoV-2 and can be orally administered. Additionally, as the site of action is considered to be different from that of remdesivir, it is expected that the combined use will improve the therapeutic effects.

TRANSLATION

Going forward, the Company will designate OBP-2001 as a lead compound and finish ensuring safety in pre-clinical trials and GMP manufacturing of investigational drugs, aiming to start clinical trials in 2021. Furthermore, the Company will also search in parallel for a "backup compound" that will be an improvement on the preceding OBP-2001.

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

The Company licensed in OBP-601 (Censavudine) 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.

5) 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 considering indications in the ophthalmic field, which is a new area of indication for OBP-801.

The status of pipeline 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 (Chugai)
		Esophageal cancer (solid tumor) In combination with anti-PD-1 antibody	Japan	Phase I
		Esophageal cancer In combination with radiation therapy and chemotherapy	Japan	Phase I (Chugai)
			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
		HCC	Japan	Phase I (Chugai)
			South Korea and Taiwan	Phase I
OBP-702	Next generation Telomelysin (Oncolytic gene therapy)	Solid tumor	Japan	Pre-clinical
OBP-2001	Therapeutic drug for novel coronavirus infection (COVID-19)	Novel coronavirus infection (COVID-19)	Worldwide	Pre-clinical
OBP-601	Censavudine Nucleoside reverse transcriptase inhibitor	Neurodegenerative diseases	U.S.	Preparing for clinical trial
		HIV infection	Europe, the U.S. and others	Phase IIb

TRANSLATION

OBP-801	HDAC inhibitor	Various types of solid tumor	U.S.	Phase I

TRANSLATION

(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 development of TelomeScan, the Company plans to continue to build at an early stage the software utilizing AI technologies, which it commissioned CYBO to develop, with the aim of increasing detection sensitivity, accuracy, and throughput, and to promote research and development together with academia including Juntendo University. Furthermore, 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