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 Fiscal Year Ended December 31, 2020 [Japanese GAAP]

February 12, 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 & Management
Email: oncolys_information@oncolys.com
Scheduled date of Annual General Meeting of Shareholders: March 25, 2021
Scheduled date of commencing dividend payments: —
Scheduled date of filing annual securities report: March 26, 2021
Availability of supplementary briefing material on financial results: No
Schedule of financial results briefing session: Scheduled (for analysts)

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

1. Financial Results for the Fiscal Year Ended December 31, 2020 (January 1, 2020 to December 31, 2020)

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

	Net sales		Operating profit		Ordinary profit		Profit	
Fiscal year ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
December 31, 2020	314	(75.9)	(1,674)	-	(1,723)	-	(2,095)	-
December 31, 2019	1,303	673.5	(511)	-	(539)	-	(912)	-

	Basic earnings per share	Diluted earnings per share	Rate of return on equity	Ordinary profit to total assets	Operating profit to net sales
Fiscal year ended	Yen	Yen	%	%	%
December 31, 2020	(145.58)	-	(77.0)	(48.0)	-
December 31, 2019	(65.55)	-	(28.7)	(13.6)	-

(Reference) Equity in earnings of affiliates: Fiscal year ended December 31, 2020: ¥- million
Fiscal year ended December 31, 2019: ¥- million

(2) Financial Position

	Total assets	Net assets	Equity ratio	Net assets per share
	Million yen	Million yen	%	Yen
As of December 31, 2020	2,796	2,003	71.4	136.43
As of December 31, 2019	4,380	3,454	78.7	240.71

(Reference) Equity: As of December 31, 2020: ¥1,995 million
As of December 31, 2019: ¥3,446 million

TRANSLATION

(3) Cash Flows

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at end of period
Fiscal year ended	Million yen	Million yen	Million yen	Million yen
December 31, 2020	(1,465)	(37)	242	1,822
December 31, 2019	(238)	(4)	1,123	3,097

2. Dividends

	Annual dividends					Total dividends	Payout ratio	Dividends to net assets
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total			
	Yen	Yen	Yen	Yen	Yen	Million yen	%	%
Fiscal year ended December 31, 2019	-	0.00	-	0.00	0.00	-	-	-
Fiscal year ended December 31, 2020	-	0.00	-	0.00	0.00	-	-	-
Fiscal year ending December 31, 2021 (Forecast)	-	0.00	-	0.00	0.00		-	

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 earning 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) The earnings forecast for the fiscal year ending December 2021 is disclosed in a range format because it is unrealistic to forecast them with specific figures.

*** Notes:**

(1) 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

(2) Total number of issued shares (common shares)

1) Total number of issued shares at the end of the period (including treasury shares):
December 31, 2020: 14,641,900 shares
December 31, 2019: 14,331,300 shares

2) Total number of treasury shares at the end of the period:
December 31, 2020: 14,462 shares
December 31, 2019: 15,000 shares

3) Average number of shares during the period:
Fiscal year ended December 31, 2020: 14,391,621 shares

TRANSLATION

Fiscal year ended December 31, 2019: 13,917,336 shares

* These financial results are outside the scope of audit 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, please see "1. Overview of Business Results, etc. (4) Future Outlook" on page 4 of the supplementary material.

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1. Overview of Business Results, etc.

(1) Overview of Business Results for the Fiscal Year Under Review

The Japanese economy during the fiscal year ended December 31, 2020 deteriorated rapidly as economic activities slowed down globally due to the global COVID-19 pandemic. Thanks to a series of economic stimulation policies by the government, corporate performance and employment situation once showed recovery signs in general after the lifting of the state of emergency, but the outlook of the global economy became uncertain again due to the second and third waves of infections.

The trends have had a significant impact on the development of new drugs in the field of pharmaceutical research and development, where the treatment of COVID-19 patients has been prioritized and clinical trials for new drugs have been delayed.

Under these circumstances, the Company has been pursuing a vision of "Dedicating power to future cancer treatments, and Leaving our footprint in the history of cancer treatment through those achievements.", increased management efficiency and actively expanded its research, development and licensing activities. For the purpose of accelerating research and development in the pharmaceutical business, the Company 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 COVID-19 treatment. In addition, in the diagnostic business, the Company promoted research and development activities centered on TelomeScan.

For details of the Company's activities, please refer to "5. Supplemental Information (1) Research and development activities."

As a result, for the fiscal year ended December 31, 2020, net sales were ¥314,179 thousand (net sales of ¥1,303,844 thousand in the previous fiscal year), and operating loss was ¥1,674,652 thousand (operating loss of ¥511,463 thousand in the previous fiscal year). In addition, the Company recorded interest income of ¥565 thousand and other items as non-operating income, and interest expenses of ¥4,170 thousand, amortization of restricted stock remuneration of ¥13,899 thousand, share acquisition rights issuance costs of ¥9,641 thousand, share issuance costs of ¥4,152 thousand, foreign exchange losses of ¥17,556 thousand, and other items as non-operating expenses. As a result, ordinary loss was ¥1,723,537 thousand (ordinary loss of ¥539,177 thousand in the previous fiscal year).

Unleash Immuno Oncolytics, Inc. (the U.S.; hereinafter "Unleash"), whose convertible bonds the Company underwrote in February 2018, has been making progress in gene construction and characteristic analysis of new viruses. However, the execution of the business plan, including financing, has been delayed compared with the schedule presented at the time of underwriting. Taking these circumstances into account, the Company recorded Unleash's convertible bonds of ¥321,000 thousand held by the Company as a loss on valuation of investment securities, based on the exchange rate on the day of acquisition. Furthermore, the Company also recognized accrued interest on the convertible bonds of ¥35,681 thousand as bad debt expenses, based on the exchange rate as of the end of the third quarter (September 30, 2020) of the fiscal year ended December 31, 2020, and total extraordinary losses of ¥367,821 thousand. As a result, loss was ¥2,095,087 thousand (loss of ¥912,346 thousand in the previous fiscal year). The Company will enhance collaboration with Unleash and continue with the joint development towards the goal of the investment, which is to add viruses for systemic administration to the Company's pipeline and expand the adenovirus platform.

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Financial results by segment were as follows.

1) Pharmaceutical business

In the pharmaceutical business, the Company received a contractual lump-sum revenue payment of a new license agreement for OBP-601 from Transposon Therapeutics, Inc. (the U.S.; hereinafter "Transposon"), a joint development revenue from Medigen Biotechnology Corp. (Taiwan; hereinafter "Medigen") for Telomelysin, a business contract revenue from Okayama University for next generation Telomelysin OBP-702, etc. As a result, net sales were ¥313,569 thousand (net sales of ¥1,292,363 thousand in the previous fiscal year), and operating loss was ¥713,361 thousand (operating income of ¥373,069 thousand in the previous fiscal 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 ¥610 thousand (net sales of ¥11,481 thousand in the previous fiscal year), and operating loss was ¥73,346 thousand (operating loss of ¥151,655 thousand in the previous fiscal year).

(2) Overview of Financial Position for the Fiscal Year Under Review

1) Status of Assets, Liabilities and Net Assets

Assets at the end of the fiscal year under review were ¥2,796,413 thousand (36.2% decrease compared with the end of the previous fiscal year), owing partly to a decrease in cash and deposits. Liabilities were ¥793,087 thousand (14.4% decrease compared with the end of the previous fiscal year), owing partly to a decrease in accounts payable - other. Net assets were ¥2,003,325 thousand (42.0% decrease compared with the end of the previous fiscal year), owing to capital increase through issuance of new shares, loss incurred and other factors.

2) Status of Cash Flows

Cash and cash equivalents at the end of the fiscal year under review were ¥1,822,850 thousand (41.2% decrease compared with the end of the previous fiscal year). Cash flows for the fiscal year under review were as follows.

(Cash flows from operating activities)

Net cash flows used in operating activities were ¥1,465,199 thousand (a cash outflow of ¥238,228 thousand in the previous fiscal year). This is primarily attributable to loss before income taxes of ¥2,091,359 thousand, loss on valuation of investment securities of ¥321,000 thousand, share-based remuneration expenses of ¥376,608 thousand, a decrease in notes and accounts receivable - trade of ¥98,710 thousand, and an increase in accounts payable - other of ¥60,895 thousand.

(Cash flows from investing activities)

Net cash flows used in investing activities were ¥37,577 thousand (a cash outflow of ¥4,442 thousand in the previous fiscal year). This is primarily attributable to long-term loan advances of ¥21,762 thousand and payments for investments in capital of subsidiaries and associates of ¥10,763 thousand.

(Cash flows from financing activities)

Net cash flows provided by financing activities were ¥242,261 thousand (a cash inflow of ¥1,123,312 thousand in the previous fiscal year). This is primarily attributable to proceeds from issuance of common shares of ¥245,505 thousand.

TRANSLATION

(3) Overview of Cash Flows for the Fiscal Year Under Review

	Fiscal year ended December 31, 2018	Fiscal year ended December 31, 2019	Fiscal year ended December 31, 2020
Equity ratio (%)	84.3	78.7	71.4
Equity ratio based on fair value (%)	402.3	628.5	786.2
Interest-bearing liabilities to cash flows (Note 4)	—	—	—
Interest coverage ratio (Note 4)	—	—	—

Equity ratio: Equity/Total assets

Equity ratio based on fair value: Total market value of shares/Total assets

Interest-bearing liabilities to cash flows: Interest-bearing liabilities /Cash flows

Interest coverage ratio: Cash flows/Interest payments

(Note 1) Total market value of shares was calculated by multiplying the closing price on the fiscal year-end date by the number of outstanding shares on the fiscal year-end date (excluding treasury shares).

(Note 2) Operating cash flows are used as cash flows.

(Note 3) Interest-bearing liabilities include all liabilities recorded on the balance sheets for which interests are paid.

(Note 4) Figures are not presented as operating cash flows were negative.

(4) Future Outlook

For the fiscal year ending December 31, 2021, the Company forecasts net sales of 350 to 700 million yen, operating loss, ordinary loss, and net loss of 1,650 million yen to 2,000 million yen. The assumed exchange rate applied to the forecast is 105 yen to the U.S. dollar and 125 yen to the euro, respectively.

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 Telomeraisin 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 spread of covid-19 worldwide, 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).

(5) Basic Policy on Profit Distribution and Dividends for the Fiscal Year Under Review and Next Fiscal Year

As a research and development based venture, the Company has focused on upfront investments of business capital, etc., and has yet to distribute profits. However, the Company recognizes the return of profits to shareholders to be an important issue for management and will determine its dividend policy that take the operating results of each fiscal year into account, while considering further strengthening of the management foundation and the enhancement of internal reserves in preparation for further proactive business development. In accordance with this basic policy, dividend distributions are not scheduled for the fiscal year under review or the next fiscal year.

TRANSLATION

2. Management Policies

(1) Basic Policy on Management

The Company conducts a research and development-oriented business as a biotech venture for drug discovery and promotes the development and commercialization of novel cancer treatment drugs utilizing highly unique adenovirus genetic modification technology, and novel cancer detection drugs.

The Company has constructed a pipeline covering everything from the discovery to the treatment of cancer, with Telomelysin virotherapy for cancer, next generation Telomelysin OBP-702, and TelomeScan for early detection and prediction of recurrence for cancer. The Company intends to continue to work on expanding its gene modification adenovirus platform and inventing new pipelines to help meet new needs of cancer treatment in the medical field.

The basic policy of the Company is to provide essential drug discovery services such that "without Oncolys, there will be trouble for the medical field, and thus the patients," and the Company will contribute to early solutions to the challenges faced by the medical field.

(2) Target Business Indicators

The Company is a research and development based biotech venture involved in drug discovery, and profits are typically expected to increase when pipelines that are currently in development are placed on the market, and when royalty revenue is received from licensees. Therefore, at the present stage, while striving to improve pipelines for expanding contractual lump-sum payments from licensees and milestone revenue and reducing financial risks to the revenue of the diagnostic business, the Company aims to use early-stage stability and profitability as business indicators.

(3) Medium- to Long-term Management Strategies

The basic strategy of the Company involves a fabless management model utilizing outsourcing in order to realize efficient progress from pre-clinical to clinical trials. Operations are performed with minimum personnel, and focus is placed on securing and cultivating personnel specializing in comprehensive project management. The Company will continue to work on securing and cultivating proactive personnel in the future and will invest personnel in the pharmaceutical business and the diagnostic business.

The pharmaceutical business conducts proof of concept (POC) studies as an evaluation index for product value gained by achieving rapid progression to the next stage in development, and by licensing to major pharmaceutical companies and biotech companies, advocates a profit model of contractual payments from business partners and the generation of royalty revenue after products are launched in the market. In addition, the Company will work to introduce new pipelines for drugs used in the treatment of intractable diseases and rare diseases that are in high demand by the medical field.

The diagnostic business currently runs a profit model which focuses on license revenue and the sales of diagnostic viruses, and in the future, the Company aims to develop a profit model that is based on providing test kits to licensees, laboratories, and medical institutions through the actualization of mass processing for specimens that satisfies the needs of the medical field.

Going forward, the Company will continue to work on rapid progression to the next stages in development, and endeavor to construct a foundation of continuous profit by implementing multiple profit models.

TRANSLATION

(4) Issues to be Addressed

The following important issues are initiated in the organizational strategy of the Company.

a. Promoting the corporate philosophy

The vision of the Company is to dedicate its power to future cancer treatments and leave its footprint in the history of cancer treatment through those achievements.

We are on an endless quest for medical “innovation.” To this end, we spare no efforts in our diligent studies of the medical sciences. One could say we are on an adventure to accomplish big things with a small number of people. We aim to challenge ourselves in projects that big companies cannot. We are focused on how many lives we can save, rather than on how much profit can be made, and we believe this mindset will bring us profit in turn. We share this mindset not only with management and employees, but also with our shareholders. We commit ourselves to transparency in management and regular information disclosure. We aspire to contribute to society, and fully comply with all laws and regulations governing our company’s behavior.

We consider it important for our management to promote our corporate philosophy among our officers and employees and build an organization that flexibly and enthusiastically executes management strategies based on this corporate philosophy. To this end, we have formulated a code of conduct which embodies this corporate philosophy, and together with instructing officers and employees to comply with this code of conduct, we proactively create opportunities for top management to speak to our officers and employees about our corporate philosophy. On top of that, we are building an organization that places primary importance on the unified sharing of information by the research and development department and business development department. In addition, the management department that manages internal resources is constantly aware of the will of our stakeholders and ensures thorough compliance. Furthermore, the internal audit department serves to enhance monitoring functions, starting with promotion of the corporate philosophy and the code of conduct.

b. Securing and cultivating personnel

The personal growth of each officer and employee is an essential element to the growth of the Company. In order to realize this, the Company actively promotes the recruitment and cultivation of personnel. Utilizing internal and external networks, the Company seeks to recruit personnel who have reliable technique, abilities, and ambitions to grow, in addition to cultivating personnel through OJT and various training programs to enhance the team structure. The Company also endeavors to improve financial results assessments and share-based remuneration systems in order to maximize the speed and quality of business operations.

c. Strengthening research and development structures

The research and development of the Company covers the whole process from the search and invention of prospective pharmaceuticals and detection drugs to pre-clinical trials and initial clinical trials, and the main role of the Company is to act as a bridge between the pre-clinical and clinical stages (i.e., translational research). Therefore, it is an important issue to secure and cultivate personnel who take responsibility as project leaders engaging primarily in planning and progress management for research and development. In order to accomplish this, the Company strives to enhance collaboration with the clinical development department of a wholly-owned subsidiary Oncolys USA Inc. (hereinafter “OUS”). Furthermore, along with incorporating advanced technologies and improving technological levels through joint research and development with research institutions, the Company actively utilizes outsourcing partners which share the corporate philosophy, and endeavors to construct low-cost and high-level research and development structures.

d. Strengthening business development department

In the field of cancer treatment drugs, the Company uses virus formulations, and aims for the commercialization of an exceedingly unique selection of products for this industry. Therefore, the Company will construct business development structures that contribute to increasing the Company’s cash flows, by securing and cultivating business development staff knowledgeable in this field, strengthening its network with pharmaceutical companies around the world, and enhancing collaboration with OUS.

TRANSLATION

e. Outsourcing strategies

In the Company business that revolves around outsourcing, efficiency improvement is an important issue. In order to strengthen relationships with outsourcing companies such as CROs (Contract Research Organizations) and CMOs (Contract Manufacturing Organizations) in securing necessary and sufficient research, development, and manufacturing capabilities, the Company instructs the whole organization to ensure a dedicated contact system through making regular visits, etc. Also, in order to ensure ideal outsourcing structures at all times, the Company will search secondary contractors and build relationships so that operations do not become dependent on any specific company in each business field.

TRANSLATION

3. Basic Stance Concerning Choice of Accounting Standards

Since the Company has not prepared consolidated financial statements, the burden of establishing a system for preparing financial statements based on international accounting standards has been taken into consideration, and the financial statements have been prepared based on Japanese standards.

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4. Financial Statements and Primary Notes

(1) Balance Sheets

(Thousand yen)

	As of December 31, 2019	As of December 31, 2020
Assets		
Current assets		
Cash and deposits	3,342,585	2,067,927
Accounts receivable – trade	169,308	70,598
Finished goods	8,504	8,434
Work in process	3,898	–
Supplies	2,515	2,038
Advance payments – other	47,737	43,354
Prepaid expenses	202,709	241,379
Short-term loans receivable from subsidiaries and associates	10,954	–
Accounts receivable – other	37,069	1,544
Consumption taxes receivable	–	95,445
Advances paid	–	14,935
Other	1,146	16
Total current assets	3,826,429	2,545,676
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	87,525
Accumulated depreciation	(61,849)	(66,207)
Tools, furniture and fixtures, net	11,823	21,317
Total property, plant and equipment	11,823	21,317
Intangible assets		
Software	850	650
Total intangible assets	850	650
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	–	31,050
Lease and guarantee deposits	27,532	21,229
Long-term prepaid expenses	82,816	63,996
Other	19	19
Total investments and other assets	540,953	228,769
Total non-current assets	553,626	250,736
Total assets	4,380,056	2,796,413

(Thousand yen)

	As of December 31, 2019	As of December 31, 2020
Liabilities		
Current liabilities		
Short-term loans payable	127,776	150,008
Lease obligations	3,147	2,144
Accounts payable – other	253,275	206,610
Accrued expenses	12,338	15,333
Income taxes payable	43,859	33,486
Accrued consumption taxes	75,828	–
Deposits received	7,576	7,661
Total current liabilities	523,801	415,244
Non-current liabilities		
Long-term loans payable	388,880	366,648
Lease obligations	8,419	6,275
Provision for retirement benefits	4,906	4,920
Total non-current liabilities	402,205	377,843
Total liabilities	926,007	793,087
Net assets		
Shareholders' equity		
Capital stock	7,121,273	7,436,537
Capital surplus		
Legal capital surplus	7,113,773	7,428,925
Other capital surplus	9,650	31,740
Total capital surpluses	7,123,423	7,460,666
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(10,806,209)	(12,901,296)
Total retained earnings	(10,806,209)	(12,901,296)
Treasury shares	–	(76)
Total shareholders' equity	3,438,488	1,995,830
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	7,750
Total net assets	3,454,048	2,003,325
Total liabilities and net assets	4,380,056	2,796,413

TRANSLATION

(2) Statements of Income

(Thousand yen)

	For the fiscal year ended December 31, 2019	For the fiscal year ended December 31, 2020
Net sales	1,303,844	314,179
Cost of sales		
Cost of service	112,891	72,205
Beginning finished goods	9,121	8,504
Cost of products manufactured	–	5,860
Total	9,121	14,365
Transfer to other account	606	70
Ending finished goods	8,504	8,434
Cost of finished goods sold	9	5,860
Gross profit	1,190,943	236,113
Selling, general and administrative expenses	1,702,406	1,910,766
Operating loss	(511,463)	(1,674,652)
Non-operating income		
Interest income	20,235	565
Dividend income	4	3
Other	217	–
Total non-operating income	20,457	568
Non-operating expenses		
Interest expenses	3,947	4,170
Amortization of restricted stock remuneration	42,108	13,899
Share acquisition rights issuance costs	–	9,641
Share issuance costs	–	4,152
Foreign exchange losses	2,115	17,556
Other	–	32
Total non-operating expenses	48,171	49,453
Ordinary loss	(539,177)	(1,723,537)
Extraordinary losses		
Bad debts expenses	9,818	35,681
Impairment loss	–	11,140
Loss on valuation of investment securities	359,597	321,000
Total extraordinary losses	369,415	367,821
Loss before income taxes	(908,593)	(2,091,359)
Income taxes – current	3,752	3,727
Total income taxes	3,752	3,727
Loss	(912,346)	(2,095,087)

TRANSLATION

(3) Detailed Schedule of Manufacturing Cost

		For the fiscal year ended December 31, 2019		For the fiscal year ended December 31, 2020	
Category	Note No.	Amount (Thousand yen)	Composition (%)	Amount (Thousand yen)	Composition (%)
I. Material cost		1,680		1,426	
II. Labor cost		979		246	
III. Expenses		1,238		289	
Total manufacturing cost		3,898		1,962	
Beginning work in process		–		3,898	
Other account received		–		–	
Total		–		5,860	
Ending work in process		3,898		–	
Transfer to other account		–		–	
Cost of products manufactured		–		5,860	

Calculation method of costs

Costs calculation methods vary based on the calculation of individual product costs.

TRANSLATION

(4) Statements of Changes in Equity

For the fiscal year ended December 31, 2019

(Thousand yen)

	Shareholders' equity							
	Capital stock	Capital surplus			Retained earnings		Treasury shares	Total shareholders' equity
		Legal capital surplus	Other capital surplus	Total capital surpluses	Other retained earnings Retained earnings brought forward	Total retained earnings		
Balance at beginning of current period	6,402,658	6,395,158	–	6,395,158	(9,893,863)	(9,893,863)	–	2,903,953
Changes of items during period								
Issuance of new shares	718,615	718,615		718,615				1,437,231
Gain on disposal of treasury stock			9,650	9,650		–		9,650
Loss					(912,346)	(912,346)		(912,346)
Purchase of treasury shares							–	–
Net changes of items other than shareholders' equity								
Total changes of items during period	718,615	718,615	9,650	728,265	(912,346)	(912,346)	0	534,535
Balance at end of current period	7,121,273	7,113,773	9,650	7,123,423	(10,806,209)	(10,806,209)	0	3,438,488

	Valuation and translation adjustments		Share acquisition rights	Total net assets
	Valuation difference on available-for-sale securities	Total valuation and translation adjustments		
Balance at beginning of current period	(13,108)	(13,108)	10,309	2,901,153
Changes of items during period				
Issuance of new shares				1,437,231
Gain on disposal of treasury stock				9,650
Loss				(912,346)
Purchase of treasury shares				
Net changes of items other than shareholders' equity	20,728	20,728	(2,369)	18,359
Total changes of items during period	20,728	20,728	(2,369)	552,895
Balance at end of current period	7,620	7,620	7,940	3,454,048

TRANSLATION

For the fiscal year ended December 31, 2020

(Thousand yen)

	Shareholders' equity							
	Capital stock	Capital surplus			Retained earnings		Treasury shares	Total shareholders' equity
		Legal capital surplus	Other capital surplus	Total capital surpluses	Other retained earnings Retained earnings brought forward	Total retained earnings		
Balance at beginning of current period	7,121,273	7,113,773	9,650	7,123,423	(10,806,209)	(10,806,209)	–	3,438,488
Changes of items during period								
Issuance of new shares	315,263	315,151		315,151				630,415
Gain on disposal of treasury stock			22,090	22,090		–		22,090
Loss					(2,095,087)	(2,095,087)		(2,095,087)
Purchase of treasury shares							(76)	(76)
Net changes of items other than shareholders' equity								
Total changes of items during period	315,263	315,151	22,090	337,242	(2,095,087)	(2,095,087)	(76)	(1,442,658)
Balance at end of current period	7,436,537	7,428,925	31,740	7,460,666	(12,901,296)	(12,901,296)	(76)	1,995,830

	Valuation and translation adjustments		Share acquisition rights	Total net assets
	Valuation difference on available-for-sale securities	Total valuation and translation adjustments		
Balance at beginning of current period	7,620	7,620	7,940	3,454,048
Changes of items during period				
Issuance of new shares				630,415
Gain on disposal of treasury stock				22,090
Loss				(2,095,087)
Purchase of treasury shares				(76)
Net changes of items other than shareholders' equity	(7,874)	(7,874)	(190)	(8,064)
Total changes of items during period	(7,874)	(7,874)	(190)	(1,450,722)
Balance at end of current period	(254)	(254)	7,750	2,003,325

TRANSLATION

(5) Statements of Cash Flows

(Thousand yen)

	For the fiscal year ended December 31, 2019	For the fiscal year ended December 31, 2020
Cash flows from operating activities		
Loss before income taxes	(908,593)	(2,091,359)
Depreciation	3,109	4,890
Bad debts expenses	9,818	35,681
Impairment loss	–	11,140
Loss (gain) on valuation of investment securities	359,597	321,000
Amortization of restricted stock remuneration	–	13,899
Share-based remuneration expenses	125,928	376,608
Increase (decrease) in provision for retirement benefits	721	13
Interest and dividend income	(20,239)	(568)
Interest expenses	3,947	4,170
Foreign exchange losses (gains)	1,349	16,844
Decrease (increase) in notes and accounts receivable – trade	(119,244)	98,710
Decrease (increase) in inventories	(3,855)	4,444
Decrease (increase) in prepaid expenses	56,471	(3,738)
Decrease (increase) in accounts receivable – other	320	(1,398)
Decrease (increase) in consumption taxes refund receivable		(95,445)
Increase (decrease) in accrued consumption taxes	75,828	(75,828)
Decrease (increase) in advance payments – other	(43,652)	4,382
Increase (decrease) in accounts payable – other	182,144	(60,895)
Other, net	44,828	(20,483)
Subtotal	(231,521)	(1,457,932)
Interest and dividend income received	875	781
Interest expenses paid	(3,829)	(4,321)
Income taxes paid	(3,752)	(3,727)
Net cash provided by (used in) operating activities	(238,228)	(1,465,199)
Cash flows from investing activities		
Payments into time deposits	(6)	(6)
Purchase of property, plant and equipment	(3,290)	(2,700)
Purchase of intangible assets	(1,000)	–
Payments for investments in capital of subsidiaries and associates	–	(10,763)
Long-term loan advances	–	(21,762)
Payments for lease and guarantee deposits	(146)	(2,346)
Net cash provided by (used in) investing activities	(4,442)	(37,577)
Cash flows from financing activities		
Proceeds from long-term loans payable	200,000	100,000
Repayments of long-term loans payable	(77,784)	(100,000)
Repayments of lease obligations	(5,795)	(3,147)
Proceeds from issuance of common shares	1,006,892	245,505
Purchase of treasury shares	–	(95)
Net cash provided by (used in) financing activities	1,123,312	242,261
Effect of exchange rate change on cash and cash equivalents	(1,201)	(14,147)
Net increase (decrease) in cash and cash equivalents	879,440	(1,274,664)
Cash and cash equivalents at beginning of year	2,218,074	3,097,514
Cash and cash equivalents at end of period	3,097,514	1,822,850

(6) Notes to Financial Statements

(Notes on going concern assumption)

There is no relevant information.

(Significant accounting policies)

1. Valuation standards and methods for securities

(1) Shares in subsidiaries and associates

Stated at cost using the moving-average method.

(2) Other securities

Fair values available

Stated at fair value based on the market value, etc. on the closing date. (Any valuation differences are directly charged or credited to net assets in full, and cost of securities sold is calculated by the moving average method.)

Fair values not available

Stated at cost using the moving-average method.

2. Valuation standards and methods of inventories

Finished goods

Stated at cost using the specific indentation method (The balance sheet value is calculated using the method of reducing book value based on decreased profitability.)

Work in process

Stated at cost using the specific indentation method (The balance sheet value is calculated using the method of reducing book value based on decreased profitability.)

Supplies

Stated at cost using the specific indentation method (The balance sheet value is calculated using the method of reducing book value based on decreased profitability.)

3. Depreciation and amortization methods for non-current assets

(1) Property, plant and equipment (excluding leased assets)

Buildings, and attached facilities and structures acquired on or after April 1, 2016 are depreciated under the straight-line method, and other property, plant and equipment are depreciated under the declining-balance method.

Major useful lives are as follows:

Buildings	3 – 15 years
Tools, furniture and fixtures	3 – 6 years

(2) Intangible assets (excluding leased assets)

Straight-line method

Software for internal use is depreciated under the straight-line method based on their estimated useful lives (5 years).

(3) Leased assets

Depreciated over respective lease periods by the straight-line method without residual value.

4. Standard for translation of foreign-currency-denominated assets or liabilities into Japanese yen

Foreign currency denominated money claims and liabilities are translated into Japanese yen at the spot exchange rates on the closing date and any conversion difference is treated as profit or loss.

TRANSLATION

5. Accounting standards for reserves

(1) Allowance for doubtful accounts

To prepare for potential credit losses on receivables, an estimated uncollectible amount is recorded at the amount calculated based on the historical rate of credit loss with respect to normal receivables, and based on the recoverability of individual cases for specified receivables such as doubtful receivables that may not be recoverable.

(2) Provision for retirement benefits

To prepare for the payment of retirement benefits to employees, a simplified method is adopted, whereby an amount to be required at year-end for voluntary termination is regarded as a retirement benefit obligation in calculating provision for retirement benefits and retirement benefit expenses.

6. Capital covered by statements of cash flows

Capital as used in the statements of cash flows comprises cash on hand, deposits available for withdrawal as needed, and short-term investments due for redemption within three months from the date of acquisition, which are easily convertible to cash and are subject to minimal risk of fluctuation in value.

7. Other important matters serving as the basis for preparing financial statements

Accounting of consumption tax, etc.

Consumption tax is accounted for by the tax exclusion method.

(Equity in earnings (losses) of affiliates if equity method is applied)

The affiliated company owned by the Company is omitted because it is an affiliated company with little importance from the profit standards and retained earnings standards.

TRANSLATION

(Segment information, etc.)

a. Segment information

1. Overview of the reportable segments

Reportable segments of the Company are determined as segments whose separate financial information is available from among the constituent units of the Company, and are regularly used by the Board of Directors to determine the allocation of management resources and to evaluate performance.

The Company classifies business according to the products and services handled, and each business department develops a comprehensive strategy and performs business activities.

The Company is therefore composed of segments separated by business content, with two reportable segments classified as the "pharmaceutical business" and the "diagnostic business."

The pharmaceutical business involves the research, development, manufacturing, sales, etc. of pharmaceutical products. The diagnostic business involves the research, development, manufacturing, sales of diagnostic drugs and devices, as well as the provision of inspection services, etc.

2. Calculation method of the amounts of net sales, profit (loss), assets, liabilities and other items by reportable segment

The accounting method used for reporting business segments is generally the same as the description in "Significant accounting policies."

Figures of profit presented in reportable segments are based on operating profit.

3. Information on net sales, profit (loss), assets, liabilities and other items by reportable segment

For the fiscal year ended December 31, 2019

(Thousand yen)

	Reportable segment			Adjustment (Note 1)	Amount recorded in Financial Statements (Note 2)
	Pharmaceutical Business	Diagnostic Business	Total		
Net sales					
Net sales to outside customers	1,292,363	11,481	1,303,844	—	1,303,844
Inter-segment net sales or transfers	—	—	—	—	—
Total	1,292,363	11,481	1,303,844	—	1,303,844
Segment profit (loss)	373,069	(151,655)	221,414	(732,877)	(511,463)
Segment assets	420,313	9,933	430,246	3,949,810	4,380,056
Other items					
Depreciation	—	303	303	2,806	3,109
Increase in property, plant and equipment, and intangible assets	—	10,237	10,237	3,290	13,527

(Notes) 1. The adjustment to segment profit (loss) of negative ¥732,877 thousand is a corporate expense that has not been allocated to reportable segments, and is mainly expenses related to administrative department that do not belong to any reportable segment.

2. The adjustment to segment assets of ¥3,949,810 thousand is a corporate asset that has not been allocated to reportable segments, and is mainly cash and deposits, etc. that do not belong to any reportable segment.

3. Segment profit (loss) has been adjusted with operating loss in financial statements.

TRANSLATION

For the fiscal year ended December 31, 2020

(Thousand yen)

	Reportable segment			Adjustment (Note 1)	Amount recorded in Financial Statements (Note 2)
	Pharmaceutical Business	Diagnostic Business	Total		
Net sales					
Net sales to outside customers	313,569	610	314,179	—	314,179
Inter-segment net sales or transfers	—	—	—	—	—
Total	313,569	610	314,179	—	314,179
Segment profit (loss)	(713,361)	(73,346)	(786,708)	(887,944)	(1,674,652)
Segment assets	91,438	21,967	113,405	2,683,008	2,796,413
Other items					
Depreciation	—	2,347	2,347	2,543	4,890
Increase in property, plant and equipment, and intangible assets	—	14,381	14,381	2,700	17,081

(Notes) 1. The adjustment to segment profit (loss) of negative ¥887,944 thousand is a corporate expense that has not been allocated to reportable segments, and is mainly expenses related to administrative department that do not belong to any reportable segment.

2. The adjustment to segment assets of ¥2,687,806 thousand is a corporate asset that has not been allocated to reportable segments, and is mainly cash and deposits, etc. that do not belong to any reportable segment.

3. Segment profit (loss) has been adjusted with operating loss in financial statements.

TRANSLATION

b. Related information

For the fiscal year ended December 31, 2019

1. Information by product and service

The information is omitted, as the segmentation of product and service is equivalent to the segmentation of reportable segments.

2. Information by geographical area

(1) Net sales

(Thousand yen)

Japan	U.S.	Other Asia	Total
1,175,753	4,481	123,609	1,303,844

(Note) Net sales are classified by country or area, based on the locations of customers.

(2) Property, plant and equipment

There is no relevant information as the Company does not have property, plant and equipment located outside Japan.

3. Information by major customer

(Thousand yen)

Name of client	Net sales	Related segment
Company A	1,175,753	Pharmaceutical business
Company B	116,609	Pharmaceutical business

(Note) The Company refrains from disclosing company names due to confidentiality clauses present in the various contracts held with customers.

TRANSLATION

For the fiscal year ended December 31, 2020

1. Information by product and service

The information is omitted, as the segmentation of product and service is equivalent to the segmentation of reportable segments.

2. Information by geographical area

(1) Net sales

(Thousand yen)

Japan	U.S.	Other Asia	Total
138,907	84,440	90,831	314,179

(Note) Net sales are classified by country or area, based on the locations of customers.

(2) Property, plant and equipment

There is no relevant information as the Company does not have property, plant and equipment located outside Japan.

3. Information by major customer

(Thousand yen)

Name of client	Net sales	Related segment
Company C	90,831	Pharmaceutical business
Company D	88,297	Pharmaceutical business

(Note) The Company refrains from disclosing company names due to confidentiality clauses present in the various contracts held with customers.

c. Information on impairment losses of non-current assets by reportable segment

There is no relevant information.

For the fiscal year ended December 31, 2020

(Thousand yen)

	Pharmaceutical Business	Diagnostic Business	Corporate	Total
Impairment loss	－	－	11,140	11,140

(Note) The “corporate” expense is an impairment loss on corporate assets that do not belong to any other segments.

d. Information on amortization amount and unamortized balance of goodwill by reportable segment

There is no relevant information.

e. Information on gain on bargain purchase by reportable segment

There is no relevant information.

TRANSLATION

(Per share information)

	For the fiscal year ended December 31, 2019	For the fiscal year ended December 31, 2020
Net assets per share	¥240.71	¥136.43
Loss per share	¥(65.55)	¥(145.58)

(Notes) 1. Diluted earnings per share are not presented because of the posting of loss per share, although there are residual shares.

2. The basis for the calculation of loss per share is as follows.

	For the fiscal year ended December 31, 2019	For the fiscal year ended December 31, 2020
Loss per share		
Loss (Thousand yen)	(912,346)	(2,095,087)
Amount not attributable to common shareholders (Thousand yen)	—	—
Loss relating to common shares (Thousand yen)	(912,346)	(2,095,087)
Average number of shares during the period (shares)	13,917,336	14,391,621

(Significant subsequent events)

There is no relevant information.

TRANSLATION

5. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the fiscal year ended December 31, 2020 totaled ¥987,242 thousand, including ¥844,805 thousand for the pharmaceutical business, ¥57,688 thousand for the diagnostic business, and ¥84,747 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 December 31, 2020, 13 persons belonged to research and development department, equivalent to 36.1% of the total number of employees.

(2) Research and development and business activities

The Company promoted research and development, and active 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 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 December 31, 2020, a total of eight clinical trials are simultaneously in progress for Telomelysin (OBP-301) virotherapy for cancer. 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. According to Chugai's disclosure materials on February 4, 2021, Chugai plans to apply for approval for Telomelysin in 2022.

Regarding the above ii) "Phase I clinical trial in combination with chemoradiotherapy for esophageal cancer," licensee Chugai has been preparing to start clinical trial for locally advanced esophageal cancer patients, with an eye toward expanding the esophageal cancer market.

TRANSLATION

Regarding the above iii) “Phase I clinical trial in combination with atezolizumab, an anti-PD-L1 antibody, and bevacizumab, a molecular targeting drug, for hepatocellular cancer,” the clinical trial was newly planned 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. The safety of administering Telomelysin alone to hepatocellular cancer patients has already been examined in the Phase I clinical trial conducted by the Company in South Korea and Taiwan.

Regarding the above iv) “Phase I clinical trial in combination with atezolizumab, an anti-PD-L1 antibody, and chemoradiotherapy for head and neck cancer,” the trial was newly planned by Chugai, and Telomelysin is administered in combination with atezolizumab, an anti-PD-L1 antibody, for head and neck cancer.

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 stage IV patients. A meeting was held in the U.S. at the end of December 2020 to review interim progress, and the Company is also considering the enrollment of esophageal cancer patients.

Regarding the above vi) “Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer,” the preparation for beginning administration was completed, led by NRG Oncology, a leading cancer research group in the U.S. The Company expects the enrollment of patients in the first half of 2021. 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 vii) “Phase II investigator-initiated clinical trial in combination with radiation therapy and pembrolizumab, an anti-PD-1 antibody, for head and neck cancer,” 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.

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, was shown. For the Phase Ib clinical trial currently in progress, enrollment of 10 among the targeted 13 patients was completed. The compilation of intermediate data, which had been scheduled for the end of 2020, has been delayed due to the spread of COVID-19 and is expected to take place in the first half of 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 next generation Telomelysin (OBP-702)

OBP-702 has two anti-tumor effects which combine the “gene 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 aims to begin clinical trials of OBP-702 by proceeding with GMP and pre-clinical trials and applying in the first half of 2022 to conduct clinical trials.

TRANSLATION

3) Activities related to OBP-2001 for COVID-19 treatment and relevant chemical compounds

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 toxicity trials. As a result, no changes were observed in general conditions, body weights, hematological/biochemical tests, and autopsy findings.

Multiple vaccines have already been approved and become viable in Europe and the U.S., indicating a commitment to early development in countries around the world. Meanwhile, it is not easy to rein in the global pandemic only by vaccination. The Company aims to develop a therapeutic drug that specifically suppresses the growth of SARS-CoV-2 and can be orally administered for patients in early stage including PCR-positive asymptomatic patients and patients with mild symptoms. Furthermore, chemical compounds that indicate activity significantly higher than OBP-2001 have already been found. The Company will identify a chemical compound with the highest potential in the first half of 2021 and promote speedy development.

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 drug 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. 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 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 start the clinical trial early.

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 exploring the potential use in the ophthalmic field, which is a new area of indication for OBP-801.

TRANSLATION

The status of pipeline in the Pharmaceutical Business is as follows.

Product	Indication	Combination therapy	Development region	Development stage
Telomelysin (OBP-301)	Esophageal cancer In combination with radiation therapy	Radiation therapy	Japan	Phase II (Chugai)
	Esophageal cancer	Radiation therapy and chemotherapy	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 Radiation therapy and chemotherapy	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-702	Solid tumor	Anti-PD-(L)1 antibody (expected)	Japan	Pre-clinical
OBP-2001	Novel coronavirus infection (COVID-19)	—	Worldwide	Pre-clinical
OBP-601 (Censavudine)	Neurodegenerative diseases	TBD	U.S.	Preparing for clinical trial
	HIV infection	—	Europe, the U.S. and others	Phase IIb (complete)
OBP-801	Various types of solid tumor	Anti-PD-(L)1 antibody (expected)	U.S.	Phase I

TRANSLATION

(b) Diagnostic business

Regarding TelomeScan, a cancer detection drug, the Company concluded a development commission agreement for automated analysis software for Circulating Tumor Cell (CTC) 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. The primary prototype of automated CTC analysis software has already been made. Going forward, the Company aims to further improve the software.

Regarding research and development, an investigator-initiated clinical research using TelomeScan is underway for CTC in the field of lung cancer with Juntendo University. Liquid Biotech USA, Inc. (hereinafter "Liquid"), licensee in the North American territory, is proceeding with joint research activities with universities and research institutions in the U.S. for applications in the fields of lung cancer and female-specific cancer. Liquid will conduct the validation of automated CTC analysis software through the use of AI.

The Company plans to continue to promote research and development together with domestic and overseas academia including Juntendo University. Furthermore, in the future, the Company will develop an improved version of the software that does not only detect CTC by using TelomeScan but also serves other purposes such as assessing the degree of malignancy of detected CTC, with a vision to upgrade its testing system to provide treatment options for patients with cancer.

TRANSLATION