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, 2021 [Japanese GAAP]

February 10, 2022

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
Email: oncolys_information@oncolys.com
Scheduled date of Annual General Meeting of Shareholders: March 30, 2022
Scheduled date of commencing dividend payments: —
Scheduled date of filing annual securities report: March 31, 2022
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, 2021 (January 1, 2021 to December 31, 2021)

(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, 2021	642	104.5	(1,454)	-	(1,500)	-	(1,615)	-
December 31, 2020	314	(75.9)	(1,674)	-	(1,723)	-	(2,095)	-

	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, 2021	(95.50)	-	(57.9)	(42.3)	-
December 31, 2020	(145.58)	-	(77.0)	(48.0)	-

(Reference) Equity in earnings of affiliates: Fiscal year ended December 31, 2021: ¥- million
Fiscal year ended December 31, 2020: ¥- million

(2) Financial Position

	Total assets	Net assets	Equity ratio	Net assets per share
	Million yen	Million yen	%	Yen
As of December 31, 2021	4,291	3,593	83.6	206.86
As of December 31, 2020	2,796	2,003	71.4	136.43

(Reference) Equity: As of December 31, 2021: ¥3,586 million
As of December 31, 2020: ¥1,995 million

(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, 2021	(1,741)	(0)	3,091	3,209
December 31, 2020	(1,465)	(37)	242	1,822

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, 2020	-	0.00	-	0.00	0.00	-	-	-
Fiscal year ended December 31, 2021	-	0.00	-	0.00	0.00	-	-	-
Fiscal year ending December 31, 2022 (Forecast)	-	0.00	-	0.00	0.00		-	

3. Financial Results Forecast for the Fiscal Year Ending December 31, 2022 (January 1, 2022 to December 31, 2022)

(% indicates changes from the previous corresponding period for the full year.)

	Net sales		Operating profit		Ordinary profit		Profit		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
Fiscal year	1,000	155.7	(1,600)	-	(1,600)	-	(1,600)	-	(94.59)

*** Notes:**

(1) 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

(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, 2021: 17,405,200 shares
  December 31, 2020: 14,641,900 shares
- 2) Total number of treasury shares at the end of the period:
  December 31, 2021: 68,494 shares
  December 31, 2020: 14,462 shares
- 3) Average number of shares during the period:
  Fiscal year ended December 31, 2021: 16,915,148 shares
  Fiscal year ended December 31, 2020: 14,391,621 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 3 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, 2021 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 another increase in infections caused by the Omicron variant.

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 globally.

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.

In particular, the Company is promoting research, development, and licensing activities with a focus on Telomelysin (OBP-301) virotherapy for cancer and OBP-2011 for the treatment of COVID-19. In addition, concerning OBP-601 (Censavudine), a nucleoside reverse transcriptase inhibitor, Transposon Therapeutics, Inc. (hereinafter "Transposon") is conducting clinical trials at its own full expense based on a license agreement.

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

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, 2021, net sales were ¥642,494 thousand (net sales of ¥314,179 thousand in the previous fiscal year), and operating loss was ¥1,454,554 thousand (operating loss of ¥1,674,652 thousand in the previous fiscal year). In addition, the Company recorded interest income of ¥494 thousand, foreign exchange gains of ¥37,369 thousand, and other items as non-operating income, and interest expenses of ¥4,169 thousand, amortization of restricted stock remuneration of ¥68,525 thousand, share acquisition rights issuance costs of ¥413 thousand, share issuance costs of ¥11,652 thousand, and other items as non-operating expenses. Ordinary loss was ¥1,500,888 thousand (ordinary loss of ¥1,723,537 thousand in the previous fiscal year). A total extraordinary loss of ¥110,825 thousand was recorded, primarily due to a loss on valuation of shares of subsidiaries and associates of Precision Corporation, a developer of vaccines for emerging infectious diseases, and an impairment loss on the Company's capital investment in TelomeScan, including fluorescence microscopes. As a result, net loss was ¥1,615,439 thousand (net loss of ¥2,095,087 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 ¥4,291,876 thousand (53.5% increase compared with the end of the previous fiscal year), owing partly to an increase in cash and deposits. Liabilities were ¥697,884 thousand (12.0% decrease compared with the end of the previous fiscal year), owing partly to a decrease in accounts payable - other. Net assets were ¥3,593,992 thousand (79.4% increase 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 ¥3,209,635 thousand (76.1% increase 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 ¥1,741,827 thousand (a cash outflow of ¥1,465,199 thousand in the previous fiscal year). This is primarily attributable to loss before income taxes of ¥1,611,714 thousand, share-based remuneration expenses of ¥208,951 thousand, extraordinary losses of ¥110,825 thousand, an increase in notes and accounts receivable - trade of ¥281,549 thousand, an increase in advance payments – other of ¥190,659, and a decrease in accounts payable - other of ¥100,336 thousand.

(Cash flows from investing activities)

Net cash flows used in investing activities were ¥942 thousand (a cash outflow of ¥37,577 thousand in the previous fiscal year). This is primarily attributable to purchase of property, plant and equipment of ¥1,437 thousand and sale of investment securities of ¥486 thousand.

(Cash flows from financing activities)

Net cash flows provided by financing activities were ¥3,091,384 thousand (a cash inflow of ¥242,261 thousand in the previous fiscal year). This is primarily attributable to proceeds from issuance of common shares of ¥3,085,424 thousand.

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

	Fiscal year ended December 31, 2019	Fiscal year ended December 31, 2020	Fiscal year ended December 31, 2021
Equity ratio (%)	78.7	71.4	83.6
Equity ratio based on fair value (%)	628.5	786.2	213.3
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, 2022, the Company forecasts net sales of 1,000 million yen, operating loss, ordinary loss, and net loss of 1,600 million yen. The Company also forecasts research and development expenses of 1,700 million yen for the fiscal year ending December 31, 2022. The forecasts ae based in assumed rates of 115 yen per U.S. dollar and 130 yen per euro.

The Company has signed new licensing agreements, including 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 Telomelysin and OBP-2011

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

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.

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 drugs such as novel cancer treatment drugs utilizing highly unique virus genetic modification technology, drugs for the treatment of serious infectious diseases, and novel cancer detection drugs.

In particular, the Company has constructed a pipeline for the field of cancer, 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, in addition to a pipeline for the serious infectious diseases field with a focus on OBP-2011 for the treatment of COVID-19. In addition, we are developing OBP-601, which has until now been developed as a treatment for HIV infection, as a treatment for intractable neurological diseases, and are aiming to grow as a virus drug discovery company. In the future, the Company intends accelerate the commercialization of each pipeline by promoting licensing activities to pharmaceutical companies, and work to invent new pipelines.

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 they are commercialized or royalty revenue is received from licensees. Therefore, the Company considers that its research and development expenses necessary to obtain Proof of Concept (POC) in the initial clinical trials, which is a measure of the product value of the pipeline, are an important business indicator.

At the present stage, while striving to maximize the value of pipelines for expanding contractual lump-sum payments from licensees and milestone revenue and reducing financial risks, the Company aims to achieve early-stage stability and profitability.

(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, with focus placed on hiring and cultivating personnel specializing in project management of drug discovery research and development. By maximizing the value of our pipeline by achieving rapid progression to the next stage in development, the Company is able to license to major pharmaceutical companies and biotech companies on better conditions, and its licensing model is based on earning contractual payments and the generation of royalty revenue after products are launched in the market. 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 profit models from multiple pipelines.

(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. In particular, as the Company's research, development and business activities are conducted both domestically and internationally, it is important to cultivate human resources with English skills and an international perspective. 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 (i.e., proof of concept), 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. The Company has its research and development system both in Japan and overseas. 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 global medical and research institutions, the Company actively utilizes outsourcing partners and endeavors to construct low-cost and high-level research and development structures.

d. Strengthening business development department

The Company defines its business fields as the field of cancer treatment drugs using virus formulations and the field of serious infectious diseases, aiming for the commercialization of exceedingly unique virus drug

discovery for this industry. Therefore, the Company will secure and cultivate talent that possesses both business skills and abundant scientific knowledge and strengthen its network with pharmaceutical companies around the world. Furthermore, by enhancing collaboration with OUS, the Company aims to generating numerous licensing opportunities and construct business development structures that can contribute to increasing its cash flows.

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.

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.

4. Financial Statements and Primary Notes

(1) Balance Sheets

(Thousand yen)

	As of December 31, 2020	As of December 31, 2021
Assets		
Current assets		
Cash and deposits	2,067,927	3,454,714
Accounts receivable – trade	70,598	352,148
Finished goods	8,434	8,434
Supplies	2,038	3,222
Advance payments – other	43,354	234,014
Prepaid expenses	241,379	120,977
Accounts receivable – other	1,544	4,179
Consumption taxes receivable	95,445	20,304
Advances paid	14,935	–
Other	16	12
Total current assets	2,545,676	4,198,008
Non-current assets		
Property, plant and equipment		
Buildings	2,794	2,794
Accumulated depreciation	(2,794)	(2,794)
Buildings, net	–	–
Tools, furniture and fixtures	87,525	65,024
Accumulated depreciation	(66,207)	(65,024)
Tools, furniture and fixtures, net	21,317	–
Total property, plant and equipment	21,317	–
Intangible assets		
Software	650	–
Total intangible assets	650	–
Investments and other assets		
Investment securities	458	–
Shares of subsidiaries and associates	111,916	20,936
Investments in capital	100	100
Long-term loans receivable from subsidiaries and associates	31,050	34,503
Lease and guarantee deposits	21,229	21,220
Long-term prepaid expenses	63,996	17,090
Other	19	19
Total investments and other assets	228,769	93,868
Total non-current assets	250,736	93,868
Total assets	2,796,413	4,291,876

(Thousand yen)

	As of December 31, 2020	As of December 31, 2021
Liabilities		
Current liabilities		
Short-term loans payable	150,008	238,880
Lease obligations	2,144	2,674
Accounts payable – other	206,610	106,247
Accrued expenses	15,333	16,846
Income taxes payable	33,486	59,242
Deposits received	7,661	6,320
Total current liabilities	415,244	430,211
Non-current liabilities		
Long-term loans payable	366,648	255,544
Lease obligations	6,275	6,372
Provision for retirement benefits	4,920	5,756
Total non-current liabilities	377,843	267,673
Total liabilities	793,087	697,884
Net assets		
Shareholders' equity		
Capital stock	7,436,537	9,039,516
Capital surplus		
Legal capital surplus	7,428,925	9,031,904
Other capital surplus	31,740	31,740
Total capital surpluses	7,460,666	9,063,645
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(12,901,296)	(14,516,735)
Total retained earnings	(12,901,296)	(14,516,735)
Treasury shares	(76)	(113)
Total shareholders' equity	1,995,830	3,586,312
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	(254)	–
Total valuation and translation adjustments	(254)	–
Share acquisition rights	7,750	7,680
Total net assets	2,003,325	3,593,992
Total liabilities and net assets	2,796,413	4,291,876

(2) Statements of Income

(Thousand yen)

	For the fiscal year ended December 31, 2020	For the fiscal year ended December 31, 2021
Net sales	314,179	642,494
Cost of sales		
Cost of service	72,205	443,690
Beginning finished goods	8,504	8,434
Cost of products manufactured	5,860	–
Total	14,365	8,434
Transfer to other account	70	–
Ending finished goods	8,434	8,434
Cost of finished goods sold	5,860	–
Gross profit	236,113	198,803
Selling, general and administrative expenses	1,910,766	1,653,357
Operating loss	(1,674,652)	(1,454,554)
Non-operating income		
Interest income	565	494
Dividend income	3	3
Foreign exchange gains	–	37,369
Other	–	776
Total non-operating income	568	38,643
Non-operating expenses		
Interest expenses	4,170	4,169
Amortization of restricted stock remuneration	13,899	68,525
Share acquisition rights issuance costs	9,641	413
Share issuance costs	4,152	11,652
Foreign exchange losses	17,556	–
Other	32	218
Total non-operating expenses	49,453	84,977
Ordinary loss	(1,723,537)	(1,500,888)
Extraordinary losses		
Bad debts expenses	35,681	–
Impairment loss	11,140	19,845
Loss on valuation of shares of subsidiaries and associates	–	90,980
Loss on valuation of investment securities	321,000	–
Total extraordinary losses	367,821	110,825
Loss before income taxes	(2,091,359)	(1,611,714)
Income taxes – current	3,727	3,725
Total income taxes	3,727	3,725
Loss	(2,095,087)	(1,615,439)

(3) Detailed Schedule of Manufacturing Cost

		For the fiscal year ended December 31, 2020		For the fiscal year ended December 31, 2021	
Category	Note No.	Amount (Thousand yen)	Composition (%)	Amount (Thousand yen)	Composition (%)
I. Material cost		1,426	72.7	–	
II. Labor cost		246	12.6	–	
III. Expenses		289	14.7	–	
Total manufacturing cost		1,962	100.0	–	
Beginning work in process		3,898		–	
Other account received		–		–	
Total		5,860		–	
Ending work in process		–		–	
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.

(4) Statements of Changes in Equity

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

For the fiscal year ended December 31, 2021

(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	7,436,537	7,428,925	31,740	7,460,666	(12,901,296)	(12,901,296)	(76)	1,995,830
Changes of items during period								
Issuance of new shares	1,602,979	1,602,979		1,602,979				3,205,958
Gain on disposal of treasury stock			–	–		–		–
Loss					(1,615,439)	(1,615,439)		(1,615,439)
Purchase of treasury shares							(36)	(36)
Net changes of items other than shareholders' equity								
Total changes of items during period	1,602,979	1,602,979	–	1,602,979	(1, 615,439)	(1, 615,439)	(36)	1,590,482
Balance at end of current period	9,039,516	9,031,904	31,740	9,063,645	(14,516,735)	(14,516,735)	(113)	3,586,312

	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	(254)	(254)	7,750	2,003,325
Changes of items during period				
Issuance of new shares				3,205,958
Gain on disposal of treasury stock				–
Loss				(1,615,439)
Purchase of treasury shares				(36)
Net changes of items other than shareholders' equity	254	254	(70)	184
Total changes of items during period	254	254	(70)	1,590,666
Balance at end of current period	–	–	7,680	3,593,992

(5) Statements of Cash Flows

(Thousand yen)

	For the fiscal year ended December 31, 2020	For the fiscal year ended December 31, 2021
Cash flows from operating activities		
Loss before income taxes	(2,091,359)	(1,611,714)
Depreciation	4,890	6,486
Bad debts expenses	35,681	–
Impairment loss	11,140	19,845
Loss on valuation of shares of subsidiaries and associates		90,980
Loss (gain) on valuation of investment securities	321,000	–
Amortization of restricted stock remuneration	–	68,525
Share-based remuneration expenses	376,608	208,951
Increase (decrease) in provision for retirement benefits	13	836
Interest and dividend income	(568)	(497)
Interest expenses	4,170	4,169
Foreign exchange losses (gains)	16,844	(41,632)
Decrease (increase) in notes and accounts receivable – trade	98,710	(281,549)
Decrease (increase) in inventories	4,444	(1,183)
Decrease (increase) in prepaid expenses	(3,738)	(32,606)
Decrease (increase) in accounts receivable – other	(1,398)	(2,538)
Decrease (increase) in consumption taxes refund receivable	(95,445)	75,450
Increase (decrease) in accrued consumption taxes	(75,828)	–
Decrease (increase) in advance payments – other	4,382	(190,659)
Increase (decrease) in accounts payable – other	(60,895)	(100,336)
Other, net	(6,584)	53,158
Subtotal	(1,457,932)	(1,734,314)
Interest and dividend income received	781	407
Interest expenses paid	(4,321)	(4,194)
Income taxes paid	(3,727)	(3,725)
Net cash provided by (used in) operating activities	(1,465,199)	(1,741,827)
Cash flows from investing activities		
Proceeds from sale of investment securities	–	486
Payments into time deposits	(6)	(1)
Purchase of property, plant and equipment	(2,700)	(1,437)
Payments for investments in capital of subsidiaries and associates	(10,763)	–
Long-term loan advances	(21,762)	–
Payments for lease and guarantee deposits	(2,346)	(71)
Proceeds from refund of lease and guarantee deposits	–	80
Net cash provided by (used in) investing activities	(37,577)	(942)
Cash flows from financing activities		
Proceeds from long-term loans payable	100,000	100,000
Repayments of long-term loans payable	(100,000)	(122,232)
Repayments of lease obligations	(3,147)	(2,609)
Proceeds from issuance of common shares	245,505	3,085,424
Proceeds from issuance of share acquisition rights	–	42,902
Purchase of treasury shares	(95)	(36)
Other payments	–	(12,065)
Net cash provided by (used in) financing activities	242,261	3,091,384
Effect of exchange rate change on cash and cash equivalents	(14,147)	38,171
Net increase (decrease) in cash and cash equivalents	(1,274,664)	1,386,785
Cash and cash equivalents at beginning of year	3,097,514	1,822,850
Cash and cash equivalents at end of period	1,822,850	3,209,635

(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 – 8 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. Accounting method for deferred assets

Share issuance costs

Charged to expenses when incurred.

5. 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.

6. 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.

7. 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.

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

(1) Accounting of consumption tax, etc.

Accounted for by the tax exclusion method.

(2) Accounting principles and procedures adopted when the provisions of relevant accounting standards, etc. are not clear

Restricted stock compensation plan

Based on the Company's restricted stock compensation plan, compensation paid to Directors and employees of the Company is accounted for as expenses over the applicable period of service.

(Additional information)

The Company has been applying the "Revised Accounting Standard for Accounting Policy Disclosures, Accounting Changes and Error Corrections" (ASBJ Statement No.24, March 31, 2020) effective from the financial statements prepared at the end the fiscal year ended December 31, 2021, and disclosing the "Accounting principles and procedures adopted when the provisions of relevant accounting standards, etc. are not clear."

(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.

(Segment information, etc.)

a. Segment information

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

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

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

Since the Company now operates as a single segment due to the change explained above, the segment information for the fiscal year ended December 31, 2020 and the fiscal year ended December 31, 2021 is omitted from this report.

b. Related information

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.
- The information is omitted, as net sales to outside customers in a single product and service segment exceed 90% of net sales on the Statements of Income.

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 A	90,831	Pharmaceutical business
Company B	88,297	Pharmaceutical business

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

For the fiscal year ended December 31, 2021

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.
   - The information is omitted, as net sales to outside customers in a single product and service segment exceed 90% of net sales on the Statements of Income.

2. Information by geographical area

(1) Net sales

(Thousand yen)

Japan	U.S.	Other Asia	Total
318,912	35,930	287,652	642,494

(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	302,707	Drug discovery business
Company D	287,652	Drug discovery 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

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

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.

(Per share information)

	For the fiscal year ended December 31, 2020	For the fiscal year ended December 31, 2021
Net assets per share	¥136.43	¥206.86
Loss per share	¥(145.58)	¥(95.50)

(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, 2020	For the fiscal year ended December 31, 2021
Loss per share		
Loss (Thousand yen)	(2,095,087)	(1,615,439)
Amount not attributable to common shareholders (Thousand yen)	—	—
Loss relating to common shares (Thousand yen)	(2,095,087)	(1,615,439)
Average number of shares during the period (shares)	14,391,621	16,915,148

5. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the fiscal year ended December 31, 2021 totaled ¥825,474 thousand.

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, 2021, 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 active business activities centered on the following projects.

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

In December 2021, the Company agreed on a license termination contract for Telomelysin with Chugai Pharmaceutical Co., Ltd. (hereinafter "Chugai"). In accordance with this contract, the Company will take over the Phase II esophageal cancer clinical trials by October 15, 2022, which Chugai is currently implementing in Japan. In the time up until that date, Chugai will proceed with the ongoing clinical trials at its own expense. In addition, regarding the costs related to GMP production development for Telomelysin, Chugai will bear approximately 50% of the costs of the invoice amount received by the Company from the contract manufacturer by October 15, 2022.

As of December 31, 2021, the following six clinical trials are under way in Japan and overseas:

i) Phase II clinical trial in combination with radiation therapy for esophageal cancer;
ii) Phase I clinical trial in combination with atezolizumab, an anti-PD-L1 antibody, and bevacizumab, a molecular targeting drug, for hepatocellular cancer;
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 investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer;
v) Phase II investigator-initiated clinical trial in combination with radiation therapy and pembrolizumab, an anti-PD-1 antibody, for head and neck cancer; and
vi) Phase I investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for solid tumors

Going forward, the Company will place the highest priority on completing the "Phase II clinical trial in combination with radiation therapy for esophageal cancer" for Telomelysin, which has been granted "SAKIGAKE designation" for regenerative medicine products in Japan, and aim to file for approval in Japan in 2024. Overseas, the Company will leverage the orphan drug designation by the U.S. Food and Drug Administration (FDA) to continue existing clinical trials while simultaneously promoting relicensing activities.

Regarding the above i) "Phase II clinical trial in combination with radiation therapy for esophageal cancer," trials are ongoing based on the SAKIGAKE designation of April 2019, and administration by Chugai to the first patient began in Japan in March 2020. The targeted number of patients to be administered is 37. The Company will take over the clinical trial from Chugai by October 15, 2022. In the time up until that date, Chugai will proceed with the clinical trial at its own expense.

Regarding the above ii) "Phase I clinical trial in combination with atezolizumab, an anti-PD-L1 antibody, and bevacizumab, a molecular targeting drug, for hepatocellular cancer," administration to the first patient began in January 2021 by Chugai as the first clinical trial where Telomelysin is administered in combination with atezolizumab, an anti-PD-L1 antibody. However, as a result of discussion with Chugai, it is scheduled to end this clinical trial by October 2022. The Company and Chugai have confirmed that the reason for terminating this trial is not problems of safety and efficacy.

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," administration to the first patient began in May 2019 led by Cornell University in the U.S. An evaluation of the efficacy and safety of Telomelysin and pembrolizumab, an anti-PD-1 antibody, will be performed for the most advanced stage IV patients. A meeting was held at the end of December 2020 to review interim progress of eight patients, for whom evaluation was possible. Evaluation for one patient indicated partial response (PR) and for another stable disease (SD). Local reaction, which does not happen when pembrolizumab alone is administered, was found for the patient who showed PR. It is considered highly likely that this is the effect of administering Telomelysin. There was no report of problematic side-effects. The Company plans to conduct an interim evaluation of the progress in 18 patients by the end of 2022 and decide whether to continue with the clinical trial.

Regarding the above iv) "Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer," NRG Oncology, a leading cancer research group in the U.S., has been leading the trial, and administration to the first patient began in December 2021 with a goal to enroll a maximum of 21 patients. Telomelysin has been designated as an orphan drug in the U.S., and this clinical trial will be conducted on that basis. Therefore, in addition to being able to consult with the FDA for advice in conducting clinical trials, the Company will be able to receive preferential treatment in the form of grants and tax credits for clinical research expenses. In addition, first-mover rights protection will be granted for seven years after the approval of Telomelysin in the U.S., and market exclusivity will be granted during that period.

Regarding the above v) "Phase II investigator-initiated clinical trial in combination with radiation therapy and pembrolizumab, an anti-PD-1 antibody, for head and neck cancer," administration to the first patient began in May 2021, led by Cornell University in the U.S. In this clinical trial, the systemic clinical effects of Telomelysin used in combination with the anti-PD-1 antibody, in addition to the synergistic local effects of the Telomelysin used in combination with radiation therapy, will be examined. The Company plans to evaluate the progress of 12 patients by the end of 2022 and decide whether to continue with the clinical trial.

Regarding the above vi) "Phase I investigator-initiated clinical trial in combination with 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 and Phase Ib clinical trials in a total 22 patients, the safety of Telomelysin in combination with pembrolizumab, an anti-PD-1 antibody, and the efficacy in local esophageal cancer for some patients, were shown. A report was received of a scheduled presentation of the content of the trial at ASCO-GI symposium in January 2022, but a report was received that the presentation had been postponed as it took longer than imagined to measure biomarkers associated with the clinical trial. This is an investigator-initiated clinical trial, and the Company refrains from checking the content of the presentation in advance.

2) Activities related to OBP-2011 for the treatment of COVID-19

The Company concluded a joint research agreement with Kagoshima University in 2006, and has promoted drug discovery research for various intractable viral diseases with a research group led by Director Masanori Baba of the Joint Research Center for Human Retrovirus Infection at Kagoshima University Campus. As a result, OBP-2001 was discovered as a chemical compound fairly effective in suppressing the growth of SARS-CoV-2, which is the virus that causes COVID-19. Based on the results of pre-clinical trials, it has been confirmed that OBP-2011 can be orally administered.

While the mechanism of orally administered COVID-19 treatments under development by pharmaceutical companies around the world is polymerase or protease inhibitors, experimental outcomes suggest the Company's OBP-2011 is a nucleocapsid inhibitor, which inhibits virus assembly, which occurs in a late stage of the virus growth. It is a new mechanism that differs from those of other treatments under development. It is expected that its effect is not affected by such factors as virus mutation.

In vitro experiment, it exhibited efficacy against all of the Variants of Concern (VOCs) designated by the World Health Organization: alpha, first detected in the U.K., gamma, first detected in Brazil, delta, first detected in India, and beta, first detected in South Africa. Moreover, the chemical compound was also confirmed to indicate the same level of activity for other coronaviruses, such as those that caused the outbreak of severe acute respiratory syndrome (SARS) in 2002 and Middle East respiratory syndrome (MERS) in 2012, as it does for the wild type, demonstrating effectiveness in suppressing the growth of a broad range of coronaviruses.

The world of the 21st century has already seen three coronavirus pandemics (SARS, MERS, COVID-19), and experts around the world anticipate more pandemics in the future. The Company aims to establish POC in the clinical trial targeting early-stage patients with an eye on applying by the end of 2022 to conduct clinical trials. The Company would like to license to a major pharmaceutical company and prepare to respond to the

next pandemic with this drug as a therapeutic drug that turns patients SARS-CoV-2 negative in a short period of time and can be orally administered.

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

The Company licensed in OBP-601 from Yale University in 2006. From 2010 to 2014, it was licensed to Bristol-Myers Squibb Co. (hereinafter "BMS"), which promoted its development up to the completion of Phase II clinical trials as a treatment drug for HIV infection. The license agreement, however, was terminated due to changes in BMS's business strategy. Later on, in June 2020, the Company concluded a new license agreement with Transposon totaling over $300 million primarily for intractable neurological diseases. Transposon achieved its first milestone in November 2020.

Transposon is currently conducting two Phase IIa clinical trials at its own full expense, one on progressive supranuclear palsy (PSP) and the other on amyotrophic lateral sclerosis (ALS) and frontotemporal degeneration (FTD). Administration to the first patient under the Phase IIa clinical trial for PSP began in November 2021. In addition, administration to the first patient under the Phase IIa clinical trial for ALS and FTD also began in January 2022. Both trials will be conducted in a double-blind, placebo-controlled setting, and results from these trials are expected to be reported by 2024.

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

OBP-702 has two anti-tumor effects, which combine the "oncogene therapy" of the powerful cancer suppressor gene p53 with the "oncolytic functions" of Telomelysin (OBP-301). In addition, a research group led by Professor Toshiyoshi Fujiwara of Department of Gastroenterological Surgery 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), reporting on results of those trials at several conferences. In particular, in an experiment on a gemcitabine-resistant pancreatic cancer cell lines using mouse models, OBP-702 used in combination with PD-L1 antibodies exhibited stronger anti-tumor effects than OBP-702 or PD-L1 antibodies administered alone. It is expected that clinical trials for combined use with PD-L1 antibodies for pancreatic cancer will be conducted in the future.

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

Regarding TelomeScan, the Company set up a "Collaborative Research Program on Minimally Invasive Cancer Detection Method Using TelomeScan," in June 2021, with Juntendo University, aimed at establishing a platform for automated detection of live Circulating Tumor Cells (CTC) within the blood of cancer patients. By making use of AI technology, the Company aims to not only reduce the time for processing test results but also improve the sensitivity of CTC image analysis and the accuracy of the tests and bring this platform to practical use in Japan.

In December 2021, the Company initiated the termination of the North American license agreement with Liquid Biotech USA, Inc. in the U.S. due to a significant delay in the company's business plan. After the completion of automated detection, the Company will conduct licensing activities with the aim of global expansion again.

(f) 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, development in the field of cancer has been suspended. On the other hand, research is being continued at the Kyoto Prefectural University of Medicine in the ophthalmic field, which is a new area of indication for OBP-801.

The development status of pipeline is as follows.

Product	Indication	Combination therapy	Development region	Development stage
Telomelysin (OBP-301) (Suratadenoturev)	Esophageal cancer	Radiation therapy	Japan	Phase II (Chugai*1)
		Chemoradiotherapy	U.S.	Phase I
	Hepatocellular cancer (HCC)	Anti-PD-L1 antibody atezolizumab Molecular targeting drug	Japan	Phase I (Chugai*2)
		—	South Korea and Taiwan	Phase I (complete)
	Head and neck cancer	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 (complete)
OBP-2011	Novel coronavirus infection (COVID-19)	TBD	Worldwide	Pre-clinical
OBP-601 (Censavudine)	Amyotrophic lateral sclerosis (ALS) / frontotemporal degeneration (FTD)	TBD	U.S.	Phase IIa
	Progressive supranuclear palsy (PSP)	TBD	U.S.	Phase IIa
	HIV infection	—	Europe, the U.S. and others	Phase IIb (complete)
OBP-702	Solid tumor	Anti-PD-(L)1 antibody (expected)	U.S./Japan	Pre-clinical
OBP-801	Solid tumor	Anti-PD-(L)1 antibody (expected)	U.S.	Phase I (complete)
	Ophthalmic field	—	Japan	Pre-clinical
TelomeScan (OBP-401)	Solid tumor	—	Japan	Clinical research

*1: Chugai is developing the product, but the Company will take over the development by October 15, 2022.
*2: Chugai is developing the product, but the development will be completed by October 15, 2022.