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, 2018 [Japanese GAAP]

February 8, 2019

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: Naoki Kobayashi, Vice President & CFO
Phone: +81-3-5472-1578
Scheduled date of Annual General Meeting of Shareholders: March 28, 2019
Scheduled date of commencing dividend payments: —
Scheduled date of filing annual securities report: March 29, 2019
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, 2018 (January 1, 2018 to December 31, 2018)

(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, 2018	168	(26.4)	(1,247)	-	(1,230)	-	(1,233)	-
December 31, 2017	229	28.5	(1,078)	-	(1,087)	-	(1,090)	-

	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, 2018	(104.55)	-	(42.5)	(35.4)	-
December 31, 2017	(106.23)	-	(39.5)	(32.6)	-

(Reference) Equity in earnings of affiliates: Fiscal year ended December 31, 2018: ¥- million
Fiscal year ended December 31, 2017: ¥- million

(2) Financial Position

	Total assets	Net assets	Equity ratio	Net assets per share
	Million yen	Million yen	%	Yen
As of December 31, 2018	3,430	2,901	84.3	216.61
As of December 31, 2017	3,526	2,931	82.9	263.54

(Reference) Equity: As of December 31, 2018: ¥2,890 million
As of December 31, 2017: ¥2,921 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, 2018	(1,187)	342	1,147	2,218
December 31, 2017	(1,096)	131	1,476	1,922

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, 2017	-	0.00	-	0.00	0.00	-	-	-
Fiscal year ended December 31, 2018	-	0.00	-	0.00	0.00	-	-	-
Fiscal year ending December 31, 2019 (Forecast)	-	0.00	-	0.00	0.00		-	

*** 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: Yes
2) Changes in accounting policies other than 1) above: No
3) Changes in accounting estimates: No
4) Retrospective restatement: No

(Note) Please see "4. Financial Statements and Primary Notes (6) Notes to Financial Statements (Changes in accounting policies)" on page 15 of the supplementary material for more information.

(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, 2018: 13,346,000 shares
December 31, 2017: 11,086,000 shares

2) Total number of treasury shares at the end of the period:
December 31, 2018: - shares
December 31, 2017: - shares

3) Average number of shares during the period:
Fiscal year ended December 31, 2018: 11,801,825 shares
Fiscal year ended December 31, 2017: 10,267,098 shares

<u>* These financial results are outside the scope of audit by certified public accountants or an audit corporation.</u>

<u>* Explanation of the proper use of financial results forecast and other notes</u>

(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. (1) Overview of Business Results for the Period under Review" on page 2 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, 2018 remains in a state of uncertainty, demonstrated by events such as the Nikkei Stock Average having fallen below ¥19,000 for the first time in 20 months, due to concerns about the future of the global economy evident in the unease surrounding the global slowdown in corporate performance which has accompanied the slowdowns in the European and Chinese economies, as well as uncertainty about the U.S. monetary policy. Meanwhile, there were a number of uplifting events in the biotech venture industry to which the Company belongs, including the news that Prof. Tasuku Honjo, a Distinguished Professor of Kyoto University Institute for Advanced Study, was awarded the Nobel Prize in Physiology or Medicine for his research.

Amid these circumstances, the Company maintained a vision of "dedicating power to future cancer treatments, and leaving our footprint in the history of cancer treatment through those achievements," and promoted the research, development and business activities for OBP-301 (Telomelysin®) virotherapy for cancer, and TelomeScan, a drug for detecting cancer.

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, 2018, net sales were ¥168,549 thousand (¥229,139 thousand in the previous fiscal year), and operating loss was ¥1,247,563 thousand (operating loss of ¥1,078,389 thousand in the previous fiscal year). In addition, the Company recorded interest income of ¥21,380 thousand and other items as non-operating income, and interest expenses of ¥2,797 thousand and foreign exchange losses of ¥1,160 thousand as non-operating expenses. As a result, ordinary loss was ¥1,230,105 thousand (ordinary loss of ¥1,087,185 thousand in the previous fiscal year), and loss was ¥1,233,846 thousand (loss of ¥1,090,703 thousand in the previous fiscal year).

Financial results by segment were as follows.

1) Pharmaceutical business

In the pharmaceutical business, the Company received joint development revenue, etc. from Medigen Biotechnology Corp. (Taiwan; hereinafter "Medigen") in response to the development of Telomelysin® and other revenues. As a result, net sales were ¥152,611 thousand (net sales of ¥196,552 thousand in the previous fiscal year), and operating loss was ¥484,618 thousand (operating loss of ¥438,213 thousand in the previous fiscal year).

2) Diagnostic business

In the diagnostic business, revenue was recorded by sales of TelomeScan to Deciphera Pharmaceuticals, LLC (the U.S.; hereinafter "Deciphera"), etc. In addition, revenue was earned based on license agreements for TelomeScan from WONIK CUBE Corp. (South Korea; hereinafter "WONIK CUBE"), to which rights were granted in the South Korean territory, and Liquid Biotech USA, Inc. (the U.S.), to which rights were granted in the North American territory. As a result, net sales were ¥15,938 thousand (net sales of ¥32,586 thousand in the previous fiscal year), and operating loss was ¥169,734 thousand (operating loss of ¥103,521 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 ¥3,430,112 thousand (2.7% decline compared with the end of the previous fiscal year), owing partly to a decline in cash and deposits. Liabilities were ¥528,959

thousand (11.0% decline compared with the end of the previous fiscal year), owing partly to repayments of loans payable. Net assets were ¥2,901,153 thousand (1.0% decline 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 ¥2,218,074 thousand (15.4% 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 ¥1,187,579 thousand (a cash outflow of ¥1,096,840 thousand in the previous fiscal year). This is primarily attributable to loss before income taxes of ¥1,230,105 thousand, a decrease in notes and accounts receivable - trade of ¥38,672 thousand, and a decrease in accounts payable - other of ¥17,868 thousand.

(Cash flows from investing activities)

Net cash flows provided by investing activities were ¥342,040 thousand (a cash inflow of ¥131,662 thousand in the previous fiscal year). This is primarily attributable to proceeds from withdrawal of time deposits of ¥700,000 thousand and purchase of investment securities of ¥356,310 thousand.

(Cash flows from financing activities)

Net cash flows provided by financing activities were ¥1,147,270 thousand (a cash inflow of ¥1,476,503 thousand in the previous fiscal year). This is primarily attributable to proceeds from issuance of common shares of ¥1,188,328 thousand and repayments of long-term loans payable of ¥33,336 thousand.

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

	Fiscal year ended December 31, 2016	Fiscal year ended December 31, 2017	Fiscal year ended December 31, 2018
Equity ratio (%)	82.7	82.9	84.3
Equity ratio based on fair value (%)	317.3	245.5	402.3
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

Focusing on furthering the development of Telomelysin®, the Company actively promotes clinical trials, non-clinical trials, and the manufacture of investigational new drugs for various domestic and international pipelines in order to further improve corporate value, and is strengthening efforts to sign license agreements with major pharmaceutical companies both in Japan and overseas. Meanwhile, the Company's base of stable

revenue is still small, and financial results fluctuate widely due to factors including contractual lump-sum revenue payments on the signing of new license agreements and development milestone revenue payments generated by events and achievements of partners with license agreements.

Given that there are currently many indeterminate factors that may influence financial results, the Company believes that it is unrealistic to attempt to calculate appropriate and realistic numerical values for financial results forecast, and therefore decided to refrain from disclosing any forecast of financial results.

(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 is involved in the development of novel cancer treatment drugs which utilize a virus genetic modification technology that is a unique platform technology, and novel cancer detection drugs. Furthermore, the Company promotes the development and commercialization of drugs for the treatment of intractable and other serious infectious diseases.

In the field of cancer in particular, the Company has constructed a pipeline covering everything from the discovery to the treatment of cancer, with OBP-301 (Telomelysin®) virotherapy for cancer, and TelomeScan for early detection and prediction of recurrence for cancer. In addition, the Company is constructing pipelines in the field of serious infectious diseases, focusing on anti-HIV drugs and drugs for the treatment of hepatitis B. Furthermore, the Company is working to expand pipelines for drugs used in the treatment of rare diseases that are in high demand by 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.

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.

(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 business 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 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. 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 continues to strive to enhance the quality and quantity of research and development department. Furthermore, along with incorporating advanced technologies through joint research and development with research institutions to improve technological levels, 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 secure and cultivate business development staff knowledgeable in this field, strengthen its network with pharmaceutical companies around the world, and construct business development structures that contribute to increasing the Company's cash flows.

e. Independent monetization of diagnostic business

The diagnostic business has signed license agreements in the two territories of South Korea and North America. However, while development will progress in each licensed country, it is expected to take several years before it will generate continuous sales. Towards establishing early-stage profitability in the diagnostic business on a fiscal year basis and realizing continuous independent profit, the Company will seek prompt expansion in global licensing territories and strive to secure future markets for test kits.

f. 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, 2017	As of December 31, 2018
Assets		
Current assets		
Cash and deposits	2,867,512	2,463,138
Accounts receivable - trade	88,736	50,063
Finished goods	11,807	9,121
Work in process	4,931	—
Supplies	1,842	1,941
Advance payments - other	12,645	4,084
Prepaid expenses	51,011	29,438
Accounts receivable - other	6,822	27,843
Consumption taxes receivable	26,116	31,755
Other	285	726
Total current assets	3,071,713	2,618,115
Non-current assets		
Property, plant and equipment		
Buildings	2,794	2,794
Accumulated depreciation	(2,794)	(2,794)
Buildings, net	—	—
Tools, furniture and fixtures	67,313	68,772
Accumulated depreciation	(64,807)	(66,516)
Tools, furniture and fixtures, net	2,506	2,256
Total property, plant and equipment	2,506	2,256
Investments and other assets		
Investment securities	400,194	668,201
Shares of subsidiaries and associates	10,173	101,153
Investments in capital	100	100
Long-term loans receivable from subsidiaries and associates	11,079	11,102
Lease and guarantee deposits	29,212	28,299
Long-term prepaid expenses	1,223	865
Other	19	19
Total investments and other assets	452,002	809,740
Total non-current assets	454,508	811,997
Total assets	3,526,222	3,430,112

(Thousand yen)

	As of December 31, 2017	As of December 31, 2018
Liabilities		
Current liabilities		
Short-term loans payable	93,336	83,336
Lease obligations	9,822	5,795
Accounts payable – other	88,740	71,012
Accrued expenses	10,959	11,845
Income taxes payable	32,826	35,933
Deposits received	3,351	4,402
Total current liabilities	239,035	212,324
Non-current liabilities		
Long-term loans payable	344,440	311,104
Lease obligations	7,140	1,345
Provision for retirement benefits	3,712	4,185
Total non-current liabilities	355,293	316,634
Total liabilities	594,328	528,959
Net assets		
Shareholders' equity		
Capital stock	5,802,444	6,402,658
Capital surplus		
Legal capital surplus	5,794,944	6,395,158
Total capital surpluses	5,794,944	6,395,158
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(8,660,016)	(9,893,863)
Total retained earnings	(8,660,016)	(9,893,863)
Total shareholders' equity	2,937,371	2,903,953
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	(15,786)	(13,108)
Total valuation and translation adjustments	(15,786)	(13,108)
Share acquisition rights	10,309	10,309
Total net assets	2,931,893	2,901,153
Total liabilities and net assets	3,526,222	3,430,112

(2) Statements of Income

(Thousand yen)

	For the fiscal year ended December 31, 2017	For the fiscal year ended December 31, 2018
Net sales	229,139	168,549
Cost of sales		
Cost of service	71,530	119,656
Beginning finished goods	13,403	11,807
Cost of products manufactured	1,655	—
Total	15,059	11,807
Transfer to other account	3,223	1,011
Ending finished goods	11,807	9,121
Cost of finished goods sold	27	1,675
Gross profit	157,581	47,217
Selling, general and administrative expenses	1,235,970	1,294,781
Operating loss	(1,078,389)	(1,247,563)
Non-operating income		
Interest income	3,887	21,380
Dividend income	4	4
Other	29	30
Total non-operating income	3,920	21,415
Non-operating expenses		
Interest expenses	3,274	2,797
Foreign exchange losses	9,441	1,160
Total non-operating expenses	12,716	3,957
Ordinary loss	(1,087,185)	(1,230,105)
Loss before income taxes	(1,087,185)	(1,230,105)
Income taxes - current	3,518	3,740
Total income taxes	3,518	3,740
Loss	(1,090,703)	(1,233,846)

(3) Detailed Schedule of Manufacturing Cost

		For the fiscal year ended December 31, 2017		For the fiscal year ended December 31, 2018	
Category	Note No.	Amount (Thousand yen)	Composition (%)	Amount (Thousand yen)	Composition (%)
Ⅰ. Material cost		2,254		—	
Ⅱ. Labor cost		1,574		—	
Ⅲ. Expenses		2,759		—	
Total manufacturing cost		6,587		—	
Beginning work in process		—		4,931	
Other account received		—		—	
Total		6,587		4,931	
Ending work in process		4,931		—	
Transfer to other account		—		4,931	
Cost of products manufactured		1,655		—	

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, 2017

(Thousand yen)

	Shareholders' equity					
	Capital stock	Capital surplus		Retained earnings		Total shareholders' equity
		Legal capital surplus	Total capital surpluses	Other retained earnings Retained earnings brought forward	Total retained earnings	
Balance at beginning of current period	5,090,981	5,083,481	5,083,481	(7,569,313)	(7,569,313)	2,605,149
Changes of items during period						
Issuance of new shares	711,462	711,462	711,462			1,422,925
Loss				(1,090,703)	(1,090,703)	(1,090,703)
Net changes of items other than shareholders' equity						
Total changes of items during period	711,462	711,462	711,462	(1,090,703)	(1,090,703)	332,221
Balance at end of current period	5,802,444	5,794,944	5,794,944	(8,660,016)	(8,660,016)	2,937,371

	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	(8,370)	(8,370)	20,604	2,617,383
Changes of items during period				
Issuance of new shares				1,422,925
Loss				(1,090,703)
Net changes of items other than shareholders' equity	(7,416)	(7,416)	(10,295)	(17,711)
Total changes of items during period	(7,416)	(7,416)	(10,295)	314,510
Balance at end of current period	(15,786)	(15,786)	10,309	2,931,893

For the fiscal year ended December 31, 2018

(Thousand yen)

	Shareholders' equity					
	Capital stock	Capital surplus		Retained earnings		Total shareholders' equity
		Legal capital surplus	Total capital surpluses	Other retained earnings	Total retained earnings	
				Retained earnings brought forward		
Balance at beginning of current period	5,802,444	5,794,944	5,794,944	(8,660,016)	(8,660,016)	2,937,371
Changes of items during period						
Issuance of new shares	600,214	600,214	600,214			1,200,428
Loss				(1,233,846)	(1,233,846)	(1,233,846)
Net changes of items other than shareholders' equity						
Total changes of items during period	600,214	600,214	600,214	(1,233,846)	(1,233,846)	(33,418)
Balance at end of current period	6,402,658	6,395,158	6,395,158	(9,893,863)	(9,893,863)	2,903,953

	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	(15,786)	(15,786)	10,309	2,931,893
Changes of items during period				
Issuance of new shares				1,200,428
Loss				(1,233,846)
Net changes of items other than shareholders' equity	2,677	2,677	—	2,677
Total changes of items during period	2,677	2,677	—	(30,740)
Balance at end of current period	(13,108)	(13,108)	10,309	2,901,153

(5) Statements of Cash Flows

(Thousand yen)

	For the fiscal year ended December 31, 2017	For the fiscal year ended December 31, 2018
Cash flows from operating activities		
Loss before income taxes	(1,087,185)	(1,230,105)
Depreciation	1,162	1,709
Increase (decrease) in provision for retirement benefits	928	472
Interest and dividend income	(3,891)	(21,384)
Interest expenses	3,274	2,797
Foreign exchange losses (gains)	7,864	6,088
Decrease (increase) in notes and accounts receivable - trade	(22,385)	38,672
Decrease (increase) in inventories	(3,463)	7,519
Decrease (increase) in accounts receivable - other	(500)	(320)
Decrease (increase) in advance payments - other	39,910	8,561
Increase (decrease) in accounts payable - other	(1,061)	(17,868)
Other, net	(26,137)	21,991
Subtotal	(1,091,485)	(1,181,864)
Interest and dividend income received	1,004	683
Interest expenses paid	(3,154)	(2,657)
Income taxes paid	(3,205)	(3,740)
Net cash provided by (used in) operating activities	(1,096,840)	(1,187,579)
Cash flows from investing activities		
Payments into time deposits	(400,006)	(6)
Proceeds from withdrawal of time deposits	600,000	700,000
Purchase of property, plant and equipment	(1,436)	(1,643)
Purchase of investment securities	(55,670)	(356,310)
Payments of long-term loans receivable	(11,079)	—
Payments for lease and guarantee deposits	(1,105)	—
Proceeds from collection of lease and guarantee deposits	960	—
Net cash provided by (used in) investing activities	131,662	342,040
Cash flows from financing activities		
Decrease in short-term loans payable	—	(10,000)
Proceeds from long-term loans payable	100,000	—
Repayments of long-term loans payable	(25,426)	(33,336)
Repayments of lease obligations	(10,701)	(9,822)
Proceeds from issuance of common shares	1,409,382	1,188,328
Proceeds from issuance of share acquisition rights	3,248	12,100
Net cash provided by (used in) financing activities	1,476,503	1,147,270
Effect of exchange rate change on cash and cash equivalents	(7,864)	(6,111)
Net increase (decrease) in cash and cash equivalents	503,461	295,619
Cash and cash equivalents at beginning of year	1,418,993	1,922,454
Cash and cash equivalents at end of period	1,922,454	2,218,074

(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.

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.

(Changes in accounting policies)

The "Practical Solution on Transactions Granting Employees and Others Stock Acquisition Rights, which Involve Considerations, with Vesting Conditions" (Practical Issues Task Force No. 36, January 12, 2018; hereinafter "PITF No. 36") and other guidelines have been applied since April 1, 2018 and transactions granting employees and others stock acquisition rights which involve consideration with vesting conditions are accounted for in accordance with the "Accounting Standard for Share-based Payment" (ASBJ Statement No. 8, December 27, 2005), etc.

However, the Company adopts PITF No. 36 in accordance with the transitional treatment specified in Article 10 (3) thereof and continually uses the previous accounting treatment for transactions granting employees and others stock acquisition rights which involve consideration with vesting conditions before the day on which PITF No. 36 was applied.

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

For the fiscal year ended December 31, 2017

There is no relevant information.

For the fiscal year ended December 31, 2018

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

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.

Assets are not allocated to business segments.

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

For the fiscal year ended December 31, 2017

(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	196,552	32,586	229,139	—	229,139
Inter-segment net sales or transfers	—	—	—	—	—
Total	196,552	32,586	229,139	—	229,139
Segment loss	(438,213)	(103,521)	(541,734)	(536,655)	(1,078,389)
Other items					
Depreciation	—	—	—	1,162	1,162

(Notes) 1. The adjustment to segment loss of negative ¥536,655 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. Segment loss has been adjusted with operating loss in financial statements.

For the fiscal year ended December 31, 2018

(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	152,611	15,938	168,549	—	168,549
Inter-segment net sales or transfers	—	—	—	—	—
Total	152,611	15,938	168,549	—	168,549
Segment loss	(484,618)	(169,734)	(654,353)	(593,210)	(1,247,563)
Other items					
Depreciation	—	—	—	1,709	1,709

(Notes) 1. The adjustment to segment loss of negative ¥593,210 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. Segment loss has been adjusted with operating loss in financial statements.

b. Related information

For the fiscal year ended December 31, 2017

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
580	13,506	215,052	229,139

(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	112,400	Pharmaceutical business
Company B	84,152	Pharmaceutical business
Company C	18,500	Diagnostic business
Company D	13,506	Diagnostic 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, 2018

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
120	12,318	156,111	168,549

(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 E	145,981	Pharmaceutical business
Company F	8,818	Diagnostic business
Company G	6,629	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.

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, 2017	For the fiscal year ended December 31, 2018
Net assets per share	¥263.54	¥216.61
Loss per share	¥(106.23)	¥(104.55)

(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, 2017	For the fiscal year ended December 31, 2018
Loss per share		
Loss (Thousand yen)	(1,090,703)	(1,233,846)
Amount not attributable to common shareholders (Thousand yen)	—	—
Loss relating to common shares (Thousand yen)	(1,090,703)	(1,233,846)
Average number of shares during the period (shares)	10,267,098	11,801,825

(Significant subsequent events)

There is no relevant information.

5. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the fiscal year ended December 31, 2018 totaled ¥605,821 thousand, including ¥420,634 thousand for the pharmaceutical business, ¥150,728 thousand for the diagnostic business, and ¥34,459 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, 2018, 17 persons belonged to research and development department, equivalent to 51.5% 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

Currently, five clinical trials are simultaneously in progress for Telomelysin® (OBP-301) virotherapy for cancer: i) investigator-initiated clinical study in combination with radiation therapy for esophageal cancer; ii) Phase I sponsor-initiated clinical trial in combination with radiation therapy for esophageal cancer; iii) investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for solid tumors; iv) Phase II for melanoma; and v) Phase I for hepatocellular cancer.

Regarding the above i) "investigator-initiated clinical study in combination with radiation therapy for esophageal cancer" where the safety and efficacy of Telomelysin® in combination with radiation therapy are evaluated for esophageal cancer patients refractory to resection through surgery and definitive chemoradiotherapy, the study has already been completed. At a meeting of the Japanese Society of Medical Oncology held in Kobe in July 2018, Dr. Toshiyoshi Fujiwara of the Department of Gastroenterological Surgery Transplant and Surgical Oncology, Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences gave a presentation that "treatment effect on the primary tumor was complete response (CR) in 8 among 13 patients and serious adverse events have not been reported."

Regarding the above ii) "Phase I sponsor-initiated clinical trial in combination with radiation therapy for esophageal cancer" whose target population is the same as those for "investigator-initiated clinical study in combination with radiation therapy for esophageal cancer," in March 2018, the Data and Safety Monitoring Committee confirmed the safety of Telomelysin® in the low-dose administration patient cohort and the Company began to administer it to the higher-dose patient cohort. This trial is being conducted at Okayama University Hospital and National Cancer Center Hospital East, and the Company intends to administer it to up to 9 patients. The scheduled completion date for this trial has been extended, but in July 2018, the Company held a workshop with domestic esophageal cancer specialists and briefings were held on the specifics of trial implementation protocol for the Phase II clinical trial in order to transition to the Phase II clinical trial as soon as possible. In addition, the Company has also been consulting with the Pharmaceuticals and Medical Devices Agency (PMDA) about the Phase II clinical trial and the PMDA approved the process performed by the Company.

Regarding the above iii) "investigator-initiated clinical trial in combination with an anti-PD-1 antibody for various types of solid tumors" where combination with anti-PD-1 immune checkpoint inhibitor pembrolizumab is evaluated for various types of solid tumors centered on esophageal cancer, administration to patients began in December 2017. At the American Society of Clinical Oncology (ASCO) meeting held in Chicago, the U.S. in June 2018, the protocol of this clinical trial was presented. In this trial, its safety, tolerability, etc. on patients with advanced or metastatic solid tumors will be evaluated and examined on up to 19 patients.

Regarding the above iv) "Phase II clinical trial for melanoma," administration to patients began in July 2017. The aim of this trial is to evaluate the efficacy, safety, and tumor immunity of Telomelysin® on unresectable or metastatic melanoma patients. This trial will be conducted at multiple facilities in the U.S., including the Atlantic Health System, and the Company plans to conduct the trial with up to 50 patients. However, this clinical trial has been more contentious than expected, and there have been great delays in the recruitment of

new cases. These circumstances are expected to continue, and considerations are being made for the evaluation of only a small number of cases.

Regarding v) Phase I clinical trial for hepatocellular cancer, a study involving both single-dose and repeated administration to 17 patients was conducted with Pusan National University (South Korea) and National Taiwan University (Taiwan) as trial sites. The scheduled completion date of the Phase I clinical trial has been delayed, as the Company plans to complete the trial during the fiscal year ending December 31, 2019.

In addition to the above, toward initiating investigator-initiated clinical trials in combination with pembrolizumab, an anti-PD-1 antibody for gastric cancer / gastroesophageal junction cancer, centered on Cornell University in the U.S., the Company submitted a clinical trial (Phase II) application to the U.S. Food and Drug Administration in August 2018, and received approval in December 2018. In January 2019, the Company entered into an investigator-initiated clinical trial agreement with Cornell University.

Furthermore, Jiangsu Hengrui Medicine Co., Ltd. (China), a licensee of research, development, manufacturing, and sales rights of Telomelysin® in China, is preparing to apply to the Chinese government (CFDA) to conduct clinical trials.

From the perspective of intellectual property rights, in May 2018, the Company entered into a license agreement with Stabilitech Biopharma Limited (head office: U.K.; hereinafter "Stabilitech") in the U.K. for the purpose of introducing storage and stability formulation technology to improve the usability of Telomelysin®. The Company aims to realize easier and simpler handling of Telomelysin® by using Stabilitech's virus stability platform technology which was not possible in the past and formulation patent of Telomelysin® will be extended to up to March 2031.

Also in the future, the Company will further and widely accumulate clinical data of Telomelysin® in the field of esophageal cancer in Japan and the U.S. to differentiate its target diseases from those for other "oncolytic virus therapies." Furthermore, the Company has been actively making presentations at both domestic and international academic conferences such as the Immuno-Oncology Summit held in Boston (the U.S.) in August 2018 and the Annual Meeting of the Japanese Cancer Association held in Osaka in September 2018 in order to enhance the presence of Telomelysin®.

The Company intends to strengthen its activities in order to sign new license agreements of Telomelysin® (OBP-301) with major pharmaceutical companies.

2) Other activities related to the pharmaceutical business

Phase I clinical trials are underway in the U.S. for OBP-801, an HDAC inhibitor licensed from Astellas Pharma, for patients with advanced solid tumors that show resistance to other forms of treatment. However, dose limiting toxicity was observed in two of six patients in cohort 3 and thus study enrollment of new patients was stopped. The Company is considering the possibility of restarting with another protocol including combinations with other drugs. Furthermore, the Company is conducting joint research with a research group from the Ophthalmology Department of the Kyoto Prefectural University of Medicine in the ophthalmic field as a new area of indication and in July 2018, applied for a patent.

The Company has lowered the development priority of the novel anti-HIV drug, OBP-601 (Censavudine), taking into consideration the current status of the anti-HIV drug market, and is currently looking for development partners. However, the HIV market is still in a state of supersaturation and the possibility of new licenses being issued has declined considerably. If it is determined that it would be impossible to enter into any new license agreements, the Company will consider returning rights for OBP-601 to Yale University, and proceed forward with the selection and integration of pipeline products.

In addition to the above, the Company is also focusing on joint research with academia and information exchange with pharmaceutical companies, in order to create pipeline products from new seeds. In addition, in February 2018, the Company made an investment in Unleash Immuno Oncolytics, Inc. (the U.S.; hereinafter "Unleash"), a U.S. biotech venture specializing in the development of novel oncolytic adenoviruses. Also, the Company made an investment in Precision Virologics Inc. (the U.S.) The Company intends to expand its future business opportunities by strengthening its relationship with these two companies, which have a pipeline of genetically modified adenoviruses and world-leading technology, expanding its platform for "genetically-modified adenoviruses," led by Telomelysin®, which the Company is researching and developing in Japan and overseas, and promoting a pipeline of products for "cancer and serious infectious diseases."

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

Development code	Trademark or name	Indication	Development region	Development stage
OBP-301	Telomelysin® (Virotherapy for cancer)	Esophageal cancer In combination with radiation therapy	Japan	Phase I
		Gastric cancer / gastroesophageal junction cancer In combination with anti-PD-1 antibody	U.S.	Phase II
		Melanoma (skin cancer)	U.S.	Phase II
		Hepatocellular cancer	South Korea and Taiwan	Phase I
		Various types of solid tumor In combination with anti-PD-1 antibody	Japan	Phase I
		Esophageal cancer In combination with radiation therapy	Japan	Clinical study (complete)
OBP-801	HDAC inhibitor	Various types of solid tumor	U.S.	Phase I
OBP-601	Censavudine (anti-HIV drug)	HIV infection	Europe, America and others	Phase IIb (complete)

(b) Diagnostic business

Regarding TelomeScan, a drug for detecting cancer, in the field of circulating tumor cells (CTC) in the blood, the Company entered into a joint research agreement with Shimane University regarding the field of female-specific cancer. The examination system will be simplified to focus on development primarily for cervical cancer, lung cancer, and pancreatic cancer. In addition, in the joint research signed in November 2017 with Juntendo University, the Company aims to confirm the synergistic effect of existing tumor markers and CTC detected by TelomeScan in the field of lung cancer.

Liquid Biotech USA, Inc. (the U.S.), to which rights were granted in the North American territory, has begun preparing for starting joint research with academia. Furthermore, Wonik Cube Corp. (South Korea) is preparing to launch a clinical trial of TelomeScan, as it aims to obtain CTC detection approval in South Korea. Furthermore, in July 2018, the patent application in relation to OBP-1101 (TelomeScan F35) was registered in Europe. In the future, the Company aims to continue actively proposing the utilization of TelomeScan in liquid biopsy for identifying cancer cells to operating companies and academia, and expanding new license agreements and sales of the cancer detection drug TelomeScan in Japan, China and Europe.