Non-consolidated Financial Results for the Three Months Ended March 31, 2018 [Japanese GAAP]

May 2, 2018

Company name: Oncolys BioPharma Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4588
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Scheduled date of commencing dividend payments: ―
Availability of supplementary briefing material on quarterly financial results: No
Schedule of quarterly financial results briefing session: No

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

1. Financial Results for the Three Months Ended March 31, 2018 (January 1, 2018 to March 31, 2018)

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

	Net sales		Operating profit		Ordinary profit		Profit	
Three months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
March 31, 2018	33	120.2	(302)	-	(310)	-	(311)	-
March 31, 2017	15	(48.0)	(235)	-	(241)	-	(242)	-

	Basic earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
March 31, 2018	(28.09)	-
March 31, 2017	(25.91)	-

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of March 31, 2018	3,148	2,596	82.1
As of December 31, 2017	3,526	2,931	82.9

(Reference) Equity: As of March 31, 2018: ¥2,586 million
As of December 31, 2017: ¥2,921 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended December 31, 2017	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2018	-				
Fiscal year ending December 31, 2018 (Forecast)		0.00	-	0.00	0.00

(Note) Revision to the forecast for dividends announced most recently: No

3. Financial Results Forecast for the Fiscal Year Ending December 31, 2018 (January 1, 2018 to December 31, 2018)

(% 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
Full year	230	0.4	(1,400)	-	(1,400)	-	(1,400)	-	(126.29)

(Note) Revision to the financial results forecast announced most recently: No

*** Notes:**

(1) Accounting policies adopted specially for the preparation of quarterly financial statements: No

(2) Changes in accounting policies, changes in accounting estimates and retrospective restatement
1) Changes in accounting policies due to the revision of accounting standards: No
2) Changes in accounting policies other than 1) above: No
3) Changes in accounting estimates: No
4) Retrospective restatement: No

(3) Total number of issued shares (common shares)
1) Total number of issued shares at the end of the period (including treasury shares):
March 31, 2018: 11,086,000 shares
December 31, 2017: 11,086,000 shares

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

3) Average number of shares during the period:
Three months ended March 31, 2018: 11,086,000 shares
Three months ended March 31, 2017: 9,362,111 shares

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

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

(Note regarding forward-looking statements, etc.)

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

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

(1) Explanation of Business Results

The Japanese economy during the three months ended March 31, 2018 trended toward moderate recovery, backed by improvements in corporate earnings and the employment environment and other factors, but the economic outlook remains uncertain, with instability in share prices and exchange rates, etc., owing partly to external factors such as the risk of trade war between the U.S. and China, caused by the U.S. Trump administration's policies and unstable conditions in the Middle East and East Asia.

Amid these circumstances, the Company endeavored to make management more efficient, and actively expanded its research, development, and licensing activities.

In the pharmaceutical business, the Company promoted research, development and licensing activities, centered on Telomelysin® (OBP-301) virotherapy for cancer and OBP-801, a novel epigenetic anticancer drug. In addition, in the diagnostic business, the Company promoted research, development and licensing activities, centered on TelomeScan (OBP-401/1101). For details of the Company's activities, please refer to "3. Supplemental Information (1) Research and development activities."

As a result, for the three months ended March 31, 2018, net sales were ¥33,874 thousand (¥15,380 thousand in the same period of the previous year), and operating loss was ¥302,664 thousand (operating loss of ¥235,115 thousand in the same period of the previous year). In addition, the Company recorded interest income of ¥3,220 thousand and other items as non-operating income, and foreign exchange losses of ¥10,263 thousand and other items as non-operating expenses. As a result, ordinary loss was ¥310,439 thousand (ordinary loss of ¥241,578 thousand in the same period of the previous year, and loss was ¥311,386 thousand (loss of ¥242,547 thousand in the same period of the previous year).

Financial results by segment were as follows.

1) Pharmaceutical business

In the pharmaceutical business, the Company recorded joint development revenue from Medigen Biotechnology Corp. (Taiwan; hereinafter "Medigen") in relation to Telomelysin® (OBP-301) virotherapy for cancer, and as a result, net sales were ¥33,754 thousand (zero net sales in the same period of the previous year), and operating loss was ¥126,686 thousand (operating loss of ¥90,802 thousand in the same period of the previous year).

2) Diagnostic business

In the diagnostic business, research-related contracted testing revenue was generated from academia in relation to TelomeScan, a drug for detecting circulating tumor cells (CTCs) in blood, and as a result, net sales were ¥120 thousand (net sales of ¥15,380 thousand in the same period of the previous year), and operating loss was ¥29,577 thousand (operating loss of ¥23,299 thousand in the same period of the previous year).

(2) Explanation of Financial Position

Status of Assets Liabilities and Net Assets

Assets at the end of the first quarter of the fiscal year under review were ¥3,148,825 thousand (10.7% decline compared with the end of the previous fiscal year), owing partly to a decline in cash and deposits. Liabilities were ¥551,994 thousand (7.1% decline compared with the end of the previous fiscal year), owing partly to a decline in accounts payable – other. Net assets were ¥2,596,831 thousand (11.4% decline compared with the end of the previous fiscal year), owing to loss incurred and other factors.

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

No revisions have been made to the full year financial results forecasts released on February 9, 2018.

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousand yen)

	As of December 31, 2017	As of March 31, 2018
Assets		
Current assets		
Cash and deposits	2,867,512	2,248,362
Accounts receivable - trade	88,736	33,754
Finished goods	11,807	11,807
Work in process	4,931	4,931
Supplies	1,842	1,542
Advance payments - other	12,645	3,094
Prepaid expenses	51,011	41,733
Accounts receivable - other	6,822	9,725
Consumption taxes receivable	26,116	7,003
Other	285	2
Total current assets	3,071,713	2,361,958
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	67,693
Accumulated depreciation	(64,807)	(65,144)
Tools, furniture and fixtures, net	2,506	2,549
Total property, plant and equipment	2,506	2,549
Investments and other assets		
Investment securities	400,194	641,848
Shares of subsidiaries and associates	10,173	101,153
Investments in capital	100	100
Long-term loans receivable from subsidiaries and associates	11,079	11,079
Lease and guarantee deposits	29,212	28,984
Long-term prepaid expenses	1,223	1,134
Other	19	19
Total investments and other assets	452,002	784,318
Total non-current assets	454,508	786,867
Total assets	3,526,222	3,148,825

(Thousand yen)

	As of December 31, 2017	As of March 31, 2018
Liabilities		
Current liabilities		
Short-term loans payable	93,336	93,336
Lease obligations	9,822	9,074
Accounts payable - other	88,740	73,451
Accrued expenses	10,959	11,299
Income taxes payable	32,826	13,018
Deposits received	3,351	6,518
Total current liabilities	239,035	206,697
Non-current liabilities		
Long-term loans payable	344,440	336,106
Lease obligations	7,140	5,197
Provision for retirement benefits	3,712	3,992
Total non-current liabilities	355,293	345,296
Total liabilities	594,328	551,994
Net assets		
Shareholders' equity		
Capital stock	5,802,444	5,802,444
Capital surplus		
Legal capital surplus	5,794,944	5,794,944
Total capital surpluses	5,794,944	5,794,944
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(8,660,016)	(8,971,403)
Total retained earnings	(8,660,016)	(8,971,403)
Total shareholders' equity	2,937,371	2,625,984
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	(15,786)	(39,462)
Total valuation and translation adjustments	(15,786)	(39,462)
Share acquisition rights	10,309	10,309
Total net assets	2,931,893	2,596,831
Total liabilities and net assets	3,526,222	3,148,825

(2) Quarterly Statements of Income

Three Months Ended March 31

(Thousand yen)

	For the three months ended March 31, 2017	For the three months ended March 31, 2018
Net sales	15,380	33,874
Cost of sales	—	28,523
Gross profit	15,380	5,350
Selling, general and administrative expenses	250,495	308,015
Operating loss	(235,115)	(302,664)
Non-operating income		
Interest income	1,049	3,220
Other	29	30
Total non-operating income	1,078	3,251
Non-operating expenses		
Interest expenses	695	762
Foreign exchange losses	6,845	10,263
Total non-operating expenses	7,541	11,026
Ordinary loss	(241,578)	(310,439)
Loss before income taxes	(241,578)	(310,439)
Income taxes - current	969	946
Total income taxes	969	946
Loss	(242,547)	(311,386)

(3) Notes to Quarterly Financial Statements

(Notes on going concern assumption)

There is no relevant information.

(Notes in the case of significant changes in shareholders' equity)

There is no relevant information.

(Segment information, etc.)

[Segment information]

I. For three months ended March 31, 2017

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

(Thousand yen)

	Reportable segment			Adjustment (Note 1)	Amount recorded in Quarterly Financial Statements (Note 2)
	Pharmaceutical Business	Diagnostic Business	Total		
Net sales					
Net sales to outside customers	—	15,380	15,380	—	15,380
Inter-segment net sales or transfers	—	—	—	—	—
Total	—	15,380	15,380	—	15,380
Segment loss	(90,802)	(23,299)	(114,101)	(121,013)	(235,115)

(Notes) 1. The adjustment to segment loss of negative ¥121,013 thousand is a corporate expense that has not been allocated to reportable segments, and is mainly expenses related to administrative departments that do not belong to any reportable segment.

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

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

There is no relevant information.

II. For three months ended March 31, 2018

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

(Thousand yen)

	Reportable segment			Adjustment (Note 1)	Amount recorded in Quarterly Financial Statements (Note 2)
	Pharmaceutical Business	Diagnostic Business	Total		
Net sales					
Net sales to outside customers	33,754	120	33,874	—	33,874
Inter-segment net sales or transfers	—	—	—	—	—
Total	33,754	120	33,874	—	33,874
Segment loss	(126,686)	(29,577)	(156,263)	(146,400)	(302,664)

(Notes) 1. The adjustment to segment loss of negative ¥146,400 thousand is a corporate expense that has not been allocated to reportable segments, and is mainly expenses related to administrative departments that do not belong to any reportable segment.

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

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

There is no relevant information.

3. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the fiscal year under review totaled ¥149,685 thousand**,** including ¥118,709 thousand for the pharmaceutical business, ¥23,955 thousand for the diagnostic business, and ¥7,020 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 March 31, 2018, 14 persons belonged to research and development departments, equivalent to 43.8% of the total number of employees.

(2) Research and development and business activities

The Company promoted research and development, and business activities centered on the following projects.

(a) Pharmaceutical business

1) Activities related to Telomelysin® (OBP-301) virotherapy for cancer

Five clinical trials are simultaneously in progress for Telomelysin® (OBP-301) virotherapy for cancer: 1) Phase I in combination with radiation therapy for esophageal cancer; 2) Phase II for melanoma; 3) Phase I/II for hepatocellular cancer; 4) investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for solid tumors; and 5) investigator-initiated clinical study in combination with radiation therapy for esophageal cancer.

Regarding the Phase I clinical trial in combination with radiation therapy for esophageal cancer, in March 2018, the Company received a report from the Data and Safety Monitoring Committee confirming the safety of Telomelysin® in the low-dose administration patient cohort. In the future, the Company intends to administer it to the higher-dose patient cohort, with continuous careful attention to safety, and complete the Phase I clinical trial. In this trial, the safety and efficacy of Telomelysin® in combination with radiation therapy will be evaluated for esophageal cancer patients refractory to resection through surgery and definitive chemoradiotherapy. This trial will be conducted at two facilities, Okayama University Hospital and National Cancer Center Hospital East, and the Company intends to administer it to up to 12 patients.

Regarding the 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.

Regarding the Phase I/II clinical trial for hepatocellular cancer, administration to 15 patients, including one-time and repeated administrations, has been completed at the facilities for conducting the trial, Pusan National University (South Korea) and National Taiwan University (Taiwan), and the Company plans to complete the Phase I clinical trial in 2018.

Regarding the investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for various types of solid tumor, centered on esophageal cancer, administration to patients began in December 2017. In this trial, its safety, tolerability, etc. on patients with progressive or metastatic solid tumors will be evaluated and examined on up to 28 patients.

The investigator-initiated clinical study of Telomelysin® in combination with radiation therapy for the same tumor type as the Phase I clinical trial in combination with radiation therapy for esophageal cancer, by Dr. Toshiyoshi Fujiwara of the Department of Gastroenterological Surgery Transplant and Surgical Oncology, Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences, was completed on a total of 13 patients. At the time of the release of these materials, the University is compiling the data.

Furthermore, in addition to the aforementioned five (5) clinical trials, the Company is preparing to commence a new clinical trial in the U.S. for the indication of esophageal cancer.

From a business perspective, the Company obtained joint development revenue from Medigen in accordance with the development of Telomelysin®. In addition, Jiangsu Hengrui Medicine Co., Ltd., to which the Company granted a license agreement in China, established a GMP manufacturing plant, began GMP manufacturing of Telomelysin®, and is preparing to apply to the Chinese government to conduct clinical trials.

2) Other activities related to the pharmaceutical business

Phase I clinical trials are underway in the U.S. for OBP-801, a novel epigenetic anticancer drug licensed from Astellas Pharma, for patients with advanced solid tumors that show resistance to other forms of treatment. Furthermore, the Company is conducting joint research with a research group from the Ophthalmology Department of the Kyoto Prefectural University of Medicine regarding the development of an ophthalmic preparation as a new area of indication.

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.

In addition to the above, the Company is also actively focusing on joint research with academia and information exchange with pharmaceutical companies, in order to create pipeline products from new pharmaceutical development seeds, including a novel drug for treating hepatitis B, and a next-generation Telomelysin candidate. 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, and also received common shares of Precision Virologics Inc. (the U.S.) held by Unleash. 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 "cancer virotherapy utilizing 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
		Melanoma (skin cancer)	U.S.	Phase II
		Hepatocellular cancer	South Korea and Taiwan	Phase I/II
		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
OBP-801	Epigenetic anticancer drug	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 November 2017, the Company and Juntendo University began joint research in the field of circulating tumor cells (CTC) in the blood, in order to automate the CTC detection system and expand the range of clinical indications. This research is being conducted as a cross-departmental research project at cancer-related departments of Juntendo University. In addition, Liquid Biotech USA, Inc. (the U.S.), to which rights were granted in the North American territory, has begun preparing for clinical trials aimed at early forecasting of relapsed lung cancer, centered on the University of Pennsylvania. Furthermore, Wonik Cube Corp. (South Korea) is preparing for pilot manufacturing of TelomeScan, as it aims to obtain CTC detection approval in South Korea. Furthermore, in February 2018, the Company received notice of allowance for a European patent in relation to OBP-1101 (TelomeScan F35).

In the future, the Company plans to continue actively proposing the utilization of TelomeScan in liquid biopsy for identifying cancer cells in the blood and peritoneal lavage fluid to operating companies and academia, and expanding new license agreements and sales of the cancer detection drug TelomeScan.