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 Three Months Ended March 31, 2019 [Japanese GAAP]

May 10, 2019

Company name: Oncolys BioPharma Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4588
URL: http://www.oncolys.com
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Scheduled date of filing quarterly securities report: May 10, 2019
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, 2019 (January 1, 2019 to March 31, 2019)

(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, 2019	48	42.8	(364)	-	(359)	-	(360)	-
March 31, 2018	33	120.2	(302)	-	(310)	-	(311)	-

	Basic earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
March 31, 2019	(26.91)	-
March 31, 2018	(28.09)	-

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of March 31, 2019	3,310	2,612	78.6
As of December 31, 2018	3,430	2,901	84.3

(Reference) Equity: As of March 31, 2019: ¥2,603 million
As of December 31, 2018: ¥2,890 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, 2018	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2019	-				
Fiscal year ending December 31, 2019 (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, 2019 (January 1, 2019 to December 31, 2019)

Given that there are currently many indeterminate factors that may influence financial results, the Company believes that it is unrealistic to attempt to calculate appropriate and realistic numerical values for financial results forecast, and therefore does not disclose any forecast of financial results.

*** Notes:**

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

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

(3) Total number of issued shares (common shares)
1) Total number of issued shares at the end of the period (including treasury shares):
March 31, 2019: 13,449,800 shares
December 31, 2018: 13,346,000 shares

2) Total number of treasury shares at the end of the period:
March 31, 2019: - shares
December 31, 2018: - shares

3) Average number of shares during the period:
Three months ended March 31, 2019: 13,385,821 shares
Three months ended March 31, 2018: 11,086,000 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, 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.

Table of Contents

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, 2019 exhibited signs of recovery in personal consumption as the employment and income environments continue to improve, but industrial production has been slowing down mainly due to the sluggish rate of exports to China. In the future, despite risks remaining in overseas demand, a trend towards moderate recovery led by domestic demand is expected to continue.

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. 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, 2019, net sales were ¥48,383 thousand (net sales of ¥33,874 thousand in the same period of the previous year), and operating loss was ¥364,582 thousand (operating loss of ¥302,664 thousand in the same period of the previous year). In addition, the Company recorded interest income of ¥6,000 thousand and other items as non-operating income, and interest expenses of ¥589 thousand and foreign exchange losses of ¥98 thousand as non-operating expenses. As a result, ordinary loss was ¥359,220 thousand (ordinary loss of ¥310,439 thousand in the same period of the previous year), and loss was ¥360,185 thousand (loss of ¥311,386 thousand in the same period of the previous year).

In addition, the Company concluded exclusive licensing and capital tie-up agreements concerning Telomelysin with Chugai Pharmaceutical Co., Ltd. (hereafter "Chugai") on April 8, 2019, the results of these agreements will contribute to financial results from the six months ending June 30, 2019 to be announced August 2019.

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 ¥48,383 thousand (net sales of ¥33,754 thousand in the same period of the previous year), and operating loss was ¥120,369 thousand (operating loss of ¥126,686 thousand in the same period of the previous year).

2) Diagnostic business

In the diagnostic business, research and development and business activities were expanded, but no net sales were generated. As a result, net sales were zero (net sales of ¥120 thousand in the same period of the previous year) and operating loss was ¥96,384 thousand (operating loss of ¥29,577 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 ¥3,310,500 thousand (3.5% decline compared with the end of the previous fiscal year), owing partly to a decline in cash and deposits. Liabilities were ¥697,528 thousand (31.9% increase compared with the end of the previous fiscal year), owing to the

execution of loans. Net assets were ¥2,612,972 thousand (9.9% decline compared with the end of the previous fiscal year), owing to capital increase through issuance of new shares, loss incurred and other factors.

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

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 does not disclose any forecast of financial results.

2. Quarterly Financial Statements and Primary Notes
(1) Quarterly Balance Sheets

(Thousand yen)

	As of December 31, 2018	As of March 31, 2019
Assets		
Current assets		
Cash and deposits	2,463,138	2,331,795
Accounts receivable – trade	50,063	48,383
Finished goods	9,121	9,121
Supplies	1,941	1,831
Advance payments – other	4,084	6,028
Prepaid expenses	29,438	26,652
Accounts receivable – other	27,843	33,338
Consumption taxes receivable	31,755	39,021
Other	726	766
Total current assets	2,618,115	2,496,940
Non-current assets		
Property, plant and equipment		
Buildings	2,794	2,794
Accumulated depreciation	(2,794)	(2,794)
Buildings, net	—	—
Tools, furniture and fixtures	68,772	70,650
Accumulated depreciation	(66,516)	(67,006)
Tools, furniture and fixtures, net	2,256	3,643
Total property, plant and equipment	2,256	3,643
Investments and other assets		
Investment securities	668,201	668,617
Shares of subsidiaries and associates	101,153	101,153
Investments in capital	100	100
Long-term loans receivable from subsidiaries and associates	11,102	11,100
Lease and guarantee deposits	28,299	28,151
Long-term prepaid expenses	865	776
Other	19	19
Total investments and other assets	809,740	809,916
Total non-current assets	811,997	813,560
Total assets	3,430,112	3,310,500

(Thousand yen)

	As of December 31, 2018	As of March 31, 2019
Liabilities		
Current liabilities		
Short-term loans payable	83,336	150,008
Lease obligations	5,795	4,327
Accounts payable – other	71,012	67,539
Accrued expenses	11,845	11,690
Income taxes payable	35,933	16,016
Deposits received	4,402	6,612
Total current liabilities	212,324	256,193
Non-current liabilities		
Long-term loans payable	311,104	436,098
Lease obligations	1,345	870
Provision for retirement benefits	4,185	4,366
Total non-current liabilities	316,634	441,334
Total liabilities	528,959	697,528
Net assets		
Shareholders' equity		
Capital stock	6,402,658	6,437,421
Deposit for subscriptions to shares	—	3,000
Capital surplus		
Legal capital surplus	6,395,158	6,429,921
Total capital surpluses	6,395,158	6,429,921
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(9,893,863)	(10,254,048)
Total retained earnings	(9,893,863)	(10,254,048)
Total shareholders' equity	2,903,953	2,616,294
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	(13,108)	(12,693)
Total valuation and translation adjustments	(13,108)	(12,693)
Share acquisition rights	10,309	9,371
Total net assets	2,901,153	2,612,972
Total liabilities and net assets	3,430,112	3,310,500

(2) Quarterly Statements of Income

Three Months Ended March 31

(Thousand yen)

	For the three months ended March 31, 2018	For the three months ended March 31, 2019
Net sales	33,874	48,383
Cost of sales	28,523	41,535
Gross profit	5,350	6,847
Selling, general and administrative expenses	308,015	371,430
Operating loss	(302,664)	(364,582)
Non-operating income		
Interest income	3,220	6,000
Other	30	50
Total non-operating income	3,251	6,050
Non-operating expenses		
Interest expenses	762	589
Foreign exchange losses	10,263	98
Total non-operating expenses	11,026	688
Ordinary loss	(310,439)	(359,220)
Loss before income taxes	(310,439)	(359,220)
Income taxes - current	946	965
Total income taxes	946	965
Loss	(311,386)	(360,185)

(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)

During the period from January 9, 2019 to March 29, 2019, the Company received payments for the exercise of stock acquisition rights. As a result, capital stock and legal capital surplus each increased by ¥34,763 thousand during the three months ended March 31, 2019, and at the end of the first quarter of the fiscal year under review, capital stock was ¥6,437,421 thousand and legal capital surplus was ¥6,429,921 thousand.

(Segment information, etc.)

[Segment information]

I. 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.

II. For three months ended March 31, 2019

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

(Thousand yen)

	Reportable segment			Adjustment (Note 1)	Amount recorded in Quarterly Financial Statements (Note 2)
	Pharmaceutical Business	Diagnostic Business	Total		
Net sales					
Net sales to outside customers	48,383	—	48,383	—	48,383
Inter-segment net sales or transfers	—	—	—	—	—
Total	48,383	—	48,383	—	48,383
Segment loss	(120,369)	(96,384)	(216,754)	(147,828)	(364,582)

(Notes) 1. The adjustment to segment loss of negative ¥147,828 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 three months ended March 31, 2019 totaled ¥188,144 thousand, including ¥99,109 thousand for the pharmaceutical business, ¥83,922 thousand for the diagnostic business, and ¥5,111 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, 2019, 18 persons belonged to research and development department, equivalent to 52.9% 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.

(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) Phase I sponsor-initiated clinical trial in combination with radiation therapy for esophageal cancer; ii) Phase I investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for solid tumors; iii) Phase II for melanoma; iv) Phase I and II for hepatocellular cancer; and v) Phase II investigator-initiated clinical trials in combination with pembrolizumab, an anti-PD-1 antibody for gastric cancer / gastroesophageal junction cancer.

In advance of the above i) “Phase I sponsor-initiated clinical trial in combination with radiation therapy for esophageal cancer”, the “investigator-initiated clinical study in combination with radiation therapy” which was conducted at Okayama University has already completed an evaluation of the safety and efficacy of Telomelysin in combination with radiation therapy for esophageal cancer patients refractory to resection through surgery and definitive chemoradiotherapy, and 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.” In addition, the same content was discussed in a plenary session at a meeting of the American Association for Cancer Research (AACR) held in Atlanta, the U.S. in April 2019.

Regarding the above i) “Phase I sponsor-initiated clinical trial in combination with radiation therapy for esophageal cancer,” in March 2019, 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. In order to transition to the Phase II clinical trial as soon as possible, the Company has been consulting with the Pharmaceuticals and Medical Devices Agency (PMDA) which approved the process performed by the Company.

In April 2019 it was recognized as a designated product under the ”SAKIGAKE Designation System” introduced by the Ministry of Health, Labour and Welfare. With this designation, it will receive prioritized consultations and pharmaceutical affairs reviews by the Pharmaceuticals and Medical Devices Agency (PMDA), and shorter premarket review period is expected.

Regarding the above ii) “Phase I 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, and with the administration of Phase Ia being completed, it transitioned to Phase Ib. A progress report of this clinical trial was presented at a meeting of the American Association for Cancer Research (AACR) held in Atlanta, the U.S. in March 2019.

Regarding the above iii) “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. and the Company plans to conduct the trial with up to 50 patients. However, there have been great delays in the recruitment of new cases, as the competition is more intense than expected. These circumstances are expected to continue, and

considerations are being made for early completion of this clinical trial by the evaluation of only a small number of cases.

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

The above v) Phase II investigator-initiated clinical trials in combination with pembrolizumab, an anti-PD-1 antibody for gastric cancer / gastroesophageal junction cancer at Cornell University in the U.S., administration to the first patient is in preparation. It will be administered to up to 37 patients, and an evaluation of the efficacy and safety of Telomelysin and pembrolizumab, an anti-PD-1 antibody, will be performed.

Furthermore, Jiangsu Hengrui Medicine Co., Ltd. (China), a licensee of research, development, manufacturing, and sales rights of Telomelysin in China, Hong Kong, and Macau, is preparing to apply to the Chinese government (National Medical Products Administration: NMPA) to conduct clinical trials.

In addition, the Company concluded exclusive licensing and capital tie-up agreements concerning Telomelysin with Chugai Pharmaceutical Co., Ltd. (hereafter "Chugai") on April 8, 2019. In these agreements, the Company granted an exclusive license, with sublicensing rights, to Chugai concerning the development, manufacturing and marketing in Japan and Taiwan for Telomelysin. Furthermore, the exclusive option rights concerning the worldwide development, manufacturing and marketing of Telomelysin that do not include China, Hong Kong, and Macau which have already been granted to Jiangsu Hengrui Medicine Co., Ltd. were granted to Chugai.

The contractual lump-sum payments of these agreements are ¥550 million, but if a certain level of efficacy has been confirmed in the clinical trial of Telomelysin and in case Chugai exercised the exclusive option rights, the total value of the licensing agreement will be ¥50.0 billion or more. In addition, after the launch of Telomelysin, the Company will receive sales royalties according to Chugai's amount of sales of Telomelysin, apart from the total value of the licensing agreement.

The results of these agreements will contribute to financial results from the six months ending June 30, 2019 to be announced August 2019.

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, the Company entered into a joint research agreement with Juntendo University in the field of circulating tumor cells (CTC) in the blood in November 2017, and considerations are being made for clinical application in the field of lung cancer. In addition, considerations are being made for clinical application in female-specific cancer at Shimane University and for pancreatic cancer at Osaka Police Hospital. 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 universities and research institutions.

In the future, the Company aims to continue actively proposing the utilization of TelomeScan in liquid biopsy for identifying cancer cells to operating companies, universities and research institutions, and expanding new license agreements and sales of the cancer detection drug TelomeScan in Japan, China and Europe.