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, 2020 [Japanese GAAP]

May 8, 2020

Company name: Oncolys BioPharma Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4588
URL: http://www.oncolys.com
Representative: Yasuo Urata, President & CEO
Contact: Keiji Yoshimura, Vice President & Management
Email: oncolys_information@oncolys.com
Scheduled date of filing quarterly securities report: May 8, 2020
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, 2020 (January 1, 2020 to March 31, 2020)

(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, 2020	70	45.2	(287)	-	(285)	-	(286)	-
March 31, 2019	48	42.8	(364)	-	(359)	-	(360)	-

	Basic earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
March 31, 2020	(19.96)	-
March 31, 2019	(26.91)	-

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of March 31, 2020	3,885	3,166	81.3
As of December 31, 2019	4,380	3,454	78.7

(Reference) Equity: As of March 31, 2020: ¥3,158 million
As of December 31, 2019: ¥3,446 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, 2019	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2020	-				
Fiscal year ending December 31, 2020 (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, 2020 (January 1, 2020 to December 31, 2020)

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 the financial results forecast and therefore has not disclosed any forecasts for 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, 2020: 14,334,300 shares
December 31, 2019: 14,331,300 shares

2) Total number of treasury shares at the end of the period:
March 31, 2020: 17,031 shares
December 31, 2019: 15,000 shares

3) Average number of shares during the period:
Three months ended March 31, 2020: 14,330,099 shares
Three months ended March 31, 2019: 13,385,821 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, 2020 was expected to face a severe decline in consumption partly due to issuance of a request for self-restraint in unnecessary outings issued by governors/mayors of local governments in order to avoid the collapse of health care systems caused by the coronavirus disease (COVID-19). The financial market is also in a more chaotic situation than that which was seen during the 2008 financial crisis, and prospects for both the Japanese and global economy are uncertain. While pharmaceutical companies are proceeding with the development of drugs and vaccines to treat or prevent the coronavirus disease (COVID-19), it will take some time for these to become viable.

Amid these circumstances, the Company endeavored to increase management efficiency and actively expanded its research, development, and licensing activities. For the purpose of accelerating research and development in the pharmaceutical business, the Company has established OPA Therapeutics Inc. (hereinafter "OPA"), a wholly-owned subsidiary of the Company in April 2020. OPA has its business location in the state of California, the U.S., and will undertake the execution of non-clinical trials. Dr. Frank Tufaro (former Chief Executive Officer of DNAtrix Inc.) who has over 20 years of experience in oncolytic virus research and development, is appointed as President of OPA.

In the pharmaceutical business, the Company promoted research, development, and licensing activities centered on Telomelysin (OBP-301) virotherapy for cancer. In addition, in the diagnostic business, the Company promoted research and development activities centered on TelomeScan (OBP-401). 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, 2020, net sales were ¥70,274 thousand (net sales of ¥48,383 thousand in the same period of the previous year), and operating loss was ¥287,690 thousand (operating loss of ¥364,582 thousand in the same period of the previous year). In addition, the Company recorded interest income of ¥5,107 thousand as non-operating income and interest expenses of ¥776 thousand, foreign exchange losses of ¥1,669 thousand, and other items as non-operating expenses. As a result, ordinary loss was ¥285,059 thousand (ordinary loss of ¥359,220 thousand in the same period of the previous year), and loss was ¥286,022 thousand (loss of ¥360,185 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 business contract revenue from Okayama University for next generation Telomelysin OBP-702 and joint development revenue from Medigen Biotechnology Corp. (Taiwan; hereinafter "Medigen") for Telomelysin. As a result, net sales were ¥70,274 thousand (net sales of ¥48,383 thousand in the same period of the previous year) and operating loss was ¥99,646 thousand (operating loss of ¥120,369 thousand in the same period of the previous year).

Going forward, the Company will proceed with Good Manufacturing Practice (GMP) and non-clinical trials for clinical trials of OBP-702 while also promoting investigator-initiated clinical trials of Telomelysin (OBP-301), which are in progress overseas.

2) Diagnostic business

In the diagnostic business, the Company is beginning clinical research with Juntendo University to consider prognosis prediction of treatment for circulating tumor cell (CTC) in the blood for patients with lung cancer and proceeded with preparation for automatic CTC test using an AI system, but no net sales were generated. As a result, net sales were zero (net sales of zero in the same period of the previous year) and operating loss was ¥13,034 thousand (operating loss of ¥96,384 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 ¥3,885,211 thousand (11.3% decline compared with the end of the previous fiscal year), owing partly to a decline in cash and deposits.

Liabilities were ¥719,070 thousand (22.3% decline compared with the end of the previous fiscal year), owing partly to a decline in accounts payable - other. Net assets were ¥3,166,140 thousand (8.3% decline compared with the end of the previous fiscal year), owing to loss incurred and other factors. Additionally, treasury shares of ¥41 thousand acquired through purchase demands from shareholders holding less than one unit were recorded in net assets.

(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 the financial results forecast and therefore has not disclosed any forecasts for financial results.

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

(Thousand yen)

	As of December 31, 2019	As of March 31, 2020
Assets		
Current assets		
Cash and deposits	3,342,585	2,974,125
Accounts receivable – trade	169,308	75,274
Finished goods	8,504	8,434
Work in process	3,898	—
Supplies	2,515	1,605
Advance payments – other	47,737	39,532
Prepaid expenses	202,709	201,231
Accounts receivable – other	37,069	41,766
Short-term loans receivable from subsidiaries and associates	10,954	10,881
Consumption taxes receivable	—	4,432
Other	1,146	1,858
Total current assets	3,826,429	3,359,143
Non-current assets		
Property, plant and equipment		
Buildings	2,794	2,794
Accumulated depreciation	(2,794)	(2,794)
Buildings, net	—	—
Tools, furniture and fixtures	73,673	74,898
Accumulated depreciation	(61,849)	(62,764)
Tools, furniture and fixtures, net	11,823	12,134
Total property, plant and equipment	11,823	12,134
Intangible assets		
Software	850	800
Total intangible assets	850	800
Investments and other assets		
Investment securities	329,333	326,888
Shares of subsidiaries and associates	101,153	101,153
Investments in capital	100	100
Long-term loans receivable from subsidiaries and associates	—	21,762
Lease and guarantee deposits	27,532	27,303
Long-term prepaid expenses	82,816	35,907
Other	19	19
Total investments and other assets	540,953	513,133
Total non-current assets	553,626	526,068
Total assets	4,380,056	3,885,211

(Thousand yen)

	As of December 31, 2019	As of March 31, 2020
Liabilities		
Current liabilities		
Short-term loans payable	127,776	150,008
Lease obligations	3,147	2,832
Accounts payable – other	253,275	87,051
Accrued expenses	12,338	9,007
Income taxes payable	43,859	19,485
Accrued consumption taxes	75,828	―
Deposits received	7,576	4,510
Total current liabilities	523,801	272,895
Non-current liabilities		
Long-term loans payable	388,880	433,320
Lease obligations	8,419	7,777
Provision for retirement benefits	4,906	5,078
Total non-current liabilities	402,205	446,175
Total liabilities	926,007	719,070
Net assets		
Shareholders' equity		
Capital stock	7,121,273	7,121,573
Capital surplus		
Legal capital surplus	7,113,773	7,114,073
Other capital surplus	9,650	9,650
Total capital surpluses	7,123,423	7,123,723
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(10,806,209)	(11,092,231)
Total retained earnings	(10,806,209)	(11,092,231)
Treasury shares	―	(41)
Total shareholders' equity	3,438,488	3,153,024
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	7,620	5,175
Total valuation and translation adjustments	7,620	5,175
Share acquisition rights	7,940	7,940
Total net assets	3,454,048	3,166,140
Total liabilities and net assets	4,380,056	3,885,211

(2) Quarterly Statements of Income

Three Months Ended March 31

(Thousand yen)

	For the three months ended March 31, 2019	For the three months ended March 31, 2020
Net sales	48,383	70,274
Cost of sales	41,535	19,506
Gross profit	6,847	50,768
Selling, general and administrative expenses	371,430	338,458
Operating loss	(364,582)	(287,690)
Non-operating income		
Interest income	6,000	5,107
Other	50	—
Total non-operating income	6,050	5,107
Non-operating expenses		
Interest expenses	589	776
Foreign exchange losses	98	1,669
Other	—	30
Total non-operating expenses	688	2,476
Ordinary loss	(359,220)	(285,059)
Loss before income taxes	(359,220)	(285,059)
Income taxes - current	965	962
Total income taxes	965	962
Loss	(360,185)	(286,022)

(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, 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.

II. For three months ended March 31, 2020

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	70,274	—	70,274	—	70,274
Inter-segment net sales or transfers	—	—	—	—	—
Total	70,274	—	70,274	—	70,274
Segment loss	(99,646)	(13,034)	(112,681)	(175,009)	(287,690)

(Notes) 1. The adjustment to segment loss of negative ¥175,009 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, 2020 totaled ¥156,053 thousand, including ¥131,142 thousand for the pharmaceutical business, ¥6,039 thousand for the diagnostic business, and ¥18,870 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, 2020, 13 persons belonged to research and development department, equivalent to 43.3% 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

The Company concluded exclusive licensing in Japan and Taiwan of Telomelysin and exclusive option right concerning the worldwide of Telomelysin, excluding Japan, Taiwan, China, Hong Kong and Macau with Chugai Pharmaceutical Co., Ltd. (hereinafter "Chugai") in April 2019. In case Chugai exercise the exclusive option right, the total amount of the license agreement the company receive from Chugai is over ¥50 billion yen, and the company has already received a contractual lump-sum payment and the first milestone revenue payment under these agreements from Chugai.

Currently, four clinical trials are simultaneously in progress for Telomelysin (OBP-301) virotherapy for cancer: i) Phase II 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 investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody for gastric cancer / gastroesophageal junction cancer; and iv) Phase I sponsor-initiated clinical trial for hepatocellular cancer.

Regarding the above i) "Phase II clinical trial in combination with radiation therapy for esophageal cancer," administration by licensee Chugai to the first patient began in Japan in March 2020. The targeted number of patients to be administered is 37 for esophageal cancer patients refractory to resection through surgery and definitive chemoradiotherapy. According to Chugai's disclosure materials on April 23, 2020, Chugai plan to apply for approval for Telomelysin in 2022.

Regarding the above ii) Phase I investigator-initiated clinical trial in combination with an anti-PD-1 antibody for various types of solid tumors in the process of the development centered on esophageal cancer in combination with pembrolizumab, an anti-PD-1 antibody, administration to patients began in December 2017.

The administration of Phase Ia clinical trials where Telomelysin was administered to the primary tumor of esophagus was completed, and it transitioned to a Phase Ib clinical trial where Telomelysin was administered to the liver metastasis site. As a result of the Phase Ia clinical trial where Telomelysin was administered to the primary tumor of esophagus, the safety of Telomelysin in combination with pembrolizumab, an anti-PD-1 antibody, was shown, and it was reported that systemic partial responses (PR) were observed in 3 out of 9 patients. For the Phase Ib clinical trial currently in progress, enrollment of 9 among the targeted 13 patients was completed. After compiling intermediate data by the end of 2020, the possibility of transition to sponsor-initiated clinical trials will be considered.

Regarding the above iii) "Phase II investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody for gastric cancer / gastroesophageal junction cancer" at Cornell University in the U.S., administration to the first patient began in May 2019. 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. The Company aims to make considerations based on a progress report on around 10 patients during 2020.

Regarding the above iv) Phase I sponsor-initiated clinical trial for hepatocellular cancer, administration of the final case was completed in April 2020 with Pusan National University (South Korea) and National Taiwan University (Taiwan) as trial sites. Going forward, the Company will compile the data and direct a future policy

by the end of 2020.

Furthermore, in the U.S., the Company is preparing for beginning Phase I investigator-initiated clinical trials on combination radiotherapy for esophageal cancer and Phase II investigator-initiated clinical trials combining the anti-PD-1 antibody and radiation therapy for head and neck cancer. In addition, the Company has been conducting non-clinical trials for breast cancer.

Jiangsu Hengrui Medicine Co., Ltd., (hereinafter "Hengrui") a licensee of research, development, manufacturing, and sales rights of Telomelysin in China, Hong Kong, and Macau, has established Good Manufacturing Practice (GMP) for Telomelysin and conducted pre-IND in October 2019, and is preparing to apply to the Chinese government (National Medical Products Administration: NMPA) to conduct clinical trials.

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

OBP-702, an oncolytic gene therapy, has two anti-tumor effects which combine the "gene therapy" of the p53 cancer suppressor gene with the "oncolytic functions" of Telomelysin (OBP-301). The Company positions OBP-702 as the "next generation Telomelysin" to follow Telomelysin itself, which has already been licensed to Chugai and Hengrui. In addition, a research group led by Professor Fujiwara of Okayama University conducted non-clinical trials on OBP-702 which was adopted as a grant program of the Japan Agency for Medical Research and Development (AMED) in April 2017 and March 2020, reporting on results of those trials at several conferences. The Company will proceed with GMP and non-clinical trials on OBP-702 and aims to begin clinical trials by 2022.

3) Other activities related to the pharmaceutical business

Regarding OBP-801, a histone deacetylase (HDAC) inhibitor licensed from Astellas Pharma Inc. in 2009, dose limiting toxicity was observed in Phase I clinical trials in the U.S., and thus, at present, study enrollment of new patients has been tentatively suspended and the Company is considering the possibility of restarting with another protocol including combinations with other drugs. Furthermore, the Company applied for a patent concerning the ophthalmic field as a new area of indication for OBP-801 in July 2018 with an ophthalmology research group from Kyoto Prefectural University of Medicine and is continuing to conduct joint research with them.

Regarding the novel anti-HIV drug, OBP-601 (Censavudine), given the current supersaturation status of the HIV market, the circumstances surrounding the possibility of new licenses being issued in the infection field are extremely harsh. Currently, the Company is actively working on business activities for concluding any new license agreements on OBP-601 in fields other than the infection field. However, if it is determined that it would be impossible to enter into any new license agreements, the Company will return rights for OBP-601 to Yale University, and proceed forward with the selection and concentration of pipeline products for effective utilization of management resources.

Regarding the project of OBP-AI-004, an antiviral agent, the Company intends to move forward with joint research with an antiviral agent research group from Kagoshima University with a view toward application development in infection fields other than the hepatitis B virus (HBV).

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 II
		Esophageal cancer (solid tumor) In combination with anti-PD-1 antibody	Japan	Phase I
		Esophageal cancer In combination with radiation therapy and chemotherapy	U.S.	Phase I (in preparation)
		Gastric / gastroesophageal junction cancer In combination with anti-PD-1 antibody	U.S.	Phase II
		Head and neck cancer In combination with anti-PD-1 antibody and radiation therapy	U.S.	Phase II (in preparation)
		HCC	South Korea and Taiwan	Phase I
OBP-801	HDAC inhibitor	Various types of solid tumor	U.S.	Phase I
OBP-601	Censavudine (anti-HIV drug)	HIV infection	Europe, the U.S. and others	Phase IIb (complete)

(b) Diagnostic business

Regarding TelomeScan, a cancer detection drug, an investor-initiated clinical research is underway for circulating tumor cell (CTC) in the blood in the field of lung cancer with Juntendo University. In addition, for applications in the field of female-specific cancer, the Company will launch a more accurate CTC testing system with detection for human papillomavirus genes from CTC of patients with cervical cancer. Liquid Biotech USA, Inc. (the U.S.), to which rights were granted in the North American territory, is proceeding with joint research activities with universities and research institutions in the U.S., and will establish a joint structure to acquire wider markets together with the Company.

In the future, the Company aims to launch an automated CTC detection system using AI, and achieve an “improvement of throughput” and “standardization of test quality”. Furthermore, the Company will enable not only detection of CTC by using TelomeScan but also gene testing for detected cells, with a vision to upgrade its testing system to provide treatment options for patients with cancer.