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 Nine Months Ended September 30, 2019 [Japanese GAAP]

November 1, 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: Keiji Yoshimura, Vice President & Management
Email: oncolys_information@oncolys.com
Scheduled date of filing quarterly securities report: November 5, 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 Nine Months Ended September 30, 2019 (January 1, 2019 to September 30, 2019)

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

	Net sales		Operating profit		Ordinary profit		Profit	
Nine months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
September 30, 2019	640	440.5	(586)	-	(587)	-	(590)	-
September 30, 2018	118	308.0	(915)	-	(899)	-	(901)	-

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2019	(42.73)	-
September 30, 2018	(79.31)	-

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of September 30, 2019	4,309	3,663	84.8
As of December 31, 2018	3,430	2,901	84.3

(Reference) Equity: As of September 30, 2019: ¥3,654 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	-	0.00	-		
Fiscal year ending December 31, 2019 (Forecast)				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):
September 30, 2019: 14,206,100 shares
December 31, 2018: 13,346,000 shares

2) Total number of treasury shares at the end of the period:
September 30, 2019: - shares
December 31, 2018: - shares

3) Average number of shares during the period:
Nine months ended September 30, 2019: 13,820,591 shares
Nine months ended September 30, 2018: 11,372,784 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.

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

(1) Explanation of Business Results

For the Japanese economy during the nine months ended September 30, 2019, economic outlook remains uncertain, with instability in share prices and foreign exchange rates, etc., owing partly to external factors, including the extreme fluctuations in oil prices and the rapid appreciation of the yen, in addition to intensifying US-China trade friction and the decelerating trend of overseas economies.

Amid these circumstances, the Company endeavored to make management more efficient and actively expanded its research, development, and licensing activities. For details of the Company's activities, please refer to "3. Supplemental Information (1) Research and development activities."

As a result, for the nine months ended September 30, 2019, net sales were ¥640,111 thousand (net sales of ¥118,422 thousand in the same period of the previous year), and operating loss was ¥586,988 thousand (operating loss of ¥915,408 thousand in the same period of the previous year). In addition, the Company recorded interest income of ¥17,648 thousand and other items as non-operating income, and amortization of restricted stock remuneration of ¥10,005 thousand, foreign exchange losses of ¥5,860 thousand and other items as non-operating expenses. As a result, ordinary loss was ¥587,805 thousand (ordinary loss of ¥899,150 thousand in the same period of the previous year), and loss was ¥590,619 thousand (loss of ¥901,951 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 contractual upfront payments received concerning the oncolytic adenovirus immunotherapy Telomelysin (OBP-301) from Chugai Pharmaceutical Co., Ltd. (hereinafter "Chugai"), joint development revenue, etc., from Medigen Biotechnology Corp. (Taiwan; hereinafter "Medigen"), and other revenues. As a result, net sales were ¥635,629 thousand (net sales of ¥113,988 thousand in the same period of the previous year), and operating profit was ¥74,010 thousand (operating loss of ¥340,123 thousand in the same period of the previous year).

2) Diagnostic business

In the diagnostic business, as a result of sales of TelomeScan, a drug for detecting circulating tumor cells (CTC) in blood, net sales were ¥4,481 thousand (net sales of ¥4,434 thousand in the same period of the previous year) and operating loss was ¥147,079 thousand (operating loss of ¥126,824 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 third quarter of the fiscal year under review were ¥4,309,304 thousand (25.6% increase compared with the end of the previous fiscal year), owing partly to an increase in cash and deposits. Liabilities were ¥645,939 thousand (22.1% increase compared with the end of the previous fiscal year), owing partly to the execution of loans. Net assets were ¥3,663,365 thousand (26.3% increase compared with the end of the previous fiscal year), owing to capital increase, loss incurred, and other factors.

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

The Company's base of stable revenue is still small, and financial results fluctuate widely due to 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 September 30, 2019
Assets		
Current assets		
Cash and deposits	2,463,138	3,021,761
Accounts receivable – trade	50,063	19,104
Finished goods	9,121	8,621
Work in process	—	1,536
Supplies	1,941	1,557
Advance payments – other	4,084	34,652
Prepaid expenses	29,438	220,731
Accounts receivable – other	27,843	31,569
Consumption taxes receivable	31,755	—
Advances paid	660	25,866
Other	66	52
Total current assets	2,618,115	3,365,454
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)	(68,237)
Tools, furniture and fixtures, net	2,256	2,413
Total property, plant and equipment	2,256	2,413
Intangible assets		
Software	—	900
Total intangible assets	—	900
Investments and other assets		
Investment securities	668,201	648,938
Shares of subsidiaries and associates	101,153	101,153
Investments in capital	100	100
Long-term loans receivable from subsidiaries and associates	11,102	10,793
Lease and guarantee deposits	28,299	27,760
Long-term prepaid expenses	865	139,683
Other	19	12,107
Total investments and other assets	809,740	940,536
Total non-current assets	811,997	943,849
Total assets	3,430,112	4,309,304

(Thousand yen)

	As of December 31, 2018	As of September 30, 2019
Liabilities		
Current liabilities		
Short-term loans payable	83,336	133,332
Lease obligations	5,795	1,688
Accounts payable – other	71,012	38,838
Accrued expenses	11,845	10,595
Income taxes payable	35,933	25,462
Accrued consumption taxes	—	26,135
Deposits received	4,402	4,722
Total current liabilities	212,324	240,774
Non-current liabilities		
Long-term loans payable	311,104	399,992
Lease obligations	1,345	368
Provision for retirement benefits	4,185	4,803
Total non-current liabilities	316,634	405,164
Total liabilities	528,959	645,939
Net assets		
Shareholders' equity		
Capital stock	6,402,658	7,089,598
Capital surplus		
Legal capital surplus	6,395,158	7,082,098
Total capital surpluses	6,395,158	7,082,098
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(9,893,863)	(10,484,482)
Total retained earnings	(9,893,863)	(10,484,482)
Total shareholders' equity	2,903,953	3,687,215
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	(13,108)	(32,371)
Total valuation and translation adjustments	(13,108)	(32,371)
Share acquisition rights	10,309	8,522
Total net assets	2,901,153	3,663,365
Total liabilities and net assets	3,430,112	4,309,304

(2) Quarterly Statements of Income

Nine Months Ended September 30

(Thousand yen)

	For the nine months ended September 30, 2018	For the nine months ended September 30, 2019
Net sales	118,422	640,111
Cost of sales	89,431	59,111
Gross profit	28,990	580,999
Selling, general and administrative expenses	944,399	1,167,988
Operating loss	(915,408)	(586,988)
Non-operating income		
Interest income	15,442	17,648
Dividend income	4	4
Foreign exchange gains	2,941	—
Other	30	217
Total non-operating income	18,418	17,869
Non-operating expenses		
Interest expenses	2,159	2,821
Amortization of restricted stock remuneration	—	10,005
Foreign exchange losses	—	5,860
Total non-operating expenses	2,159	18,686
Ordinary loss	(899,150)	(587,805)
Loss before income taxes	(899,150)	(587,805)
Income taxes - current	2,801	2,813
Total income taxes	2,801	2,813
Loss	(901,951)	(590,619)

(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)

With the receipt of payments for the exercise of stock acquisition rights during the period from January 9, 2019 to August 8, 2019, capital stock and legal capital surplus each increased by ¥72,973 thousand during the nine months ended September 30, 2019. In addition, the Company received payments for a third-party allotment from Chugai on April 24, 2019, and capital stock and legal capital surplus each increased by ¥399,981 thousand. Furthermore, pursuant to the resolution by the Board of Directors held on May 24, 2019, the Company issued new shares as restricted stock compensation on June 14, 2019, and capital stock and legal capital surplus each increased by ¥213,985 thousand.

As a result, at the end of the third quarter of the fiscal year under review, capital stock was ¥7,089,598 thousand and legal capital surplus was ¥7,082,098 thousand.

(Segment information, etc.)

[Segment information]

I. For nine months ended September 30, 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	113,988	4,434	118,422	—	118,422
Inter-segment net sales or transfers	—	—	—	—	—
Total	113,988	4,434	118,422	—	118,422
Segment loss	(340,123)	(126,824)	(466,948)	(448,460)	(915,408)

(Notes) 1. The adjustment to segment loss of negative ¥448,460 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 nine months ended September 30, 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	635,629	4,481	640,111	—	640,111
Inter-segment net sales or transfers	—	—	—	—	—
Total	635,629	4,481	640,111	—	640,111
Segment profit (loss)	74,010	(147,079)	(73,068)	(513,919)	(586,988)

(Notes) 1. The adjustment to segment profit (loss) of negative ¥513,919 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 profit (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 nine months ended September 30, 2019 totaled ¥409,185 thousand, including ¥258,193 thousand for the pharmaceutical business, ¥122,035 thousand for the diagnostic business, and ¥28,956 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 September 30, 2019, 15 persons belonged to research and development department, equivalent to 42.9% 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 the oncolytic adenovirus immunotherapy Telomelysin (OBP-301)

The Company concluded exclusive licensing and capital tie-up agreements concerning Telomelysin with 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, exclusive option rights concerning worldwide development, manufacturing, and marketing of Telomelysin that do not include China, Hong Kong, and Macau were granted to Chugai. The contractual upfront payments of these agreements are ¥550 million, but if a certain level of efficacy has been confirmed in the clinical trial of Telomelysin and if Chugai exercises its exclusive option rights, the total value of the licensing agreement Oncolys is entitled to receive will be ¥50 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. Through conclusion of these agreements, and if option agreements are included, the grant of exclusive rights concerning the development, manufacturing, and marketing of Telomelysin has been completed worldwide.

In addition to the business activities, currently, four clinical trials are simultaneously in progress for the oncolytic adenovirus immunotherapy Telomelysin (OBP-301): 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 investigator-initiated clinical trials in combination with pembrolizumab, an anti-PD-1 antibody for gastric cancer / gastroesophageal junction cancer; and iv) Phase I/II for hepatocellular cancer (HCC). Furthermore, the Company is preparing for beginning Phase II clinical trials combining the anti-PD-1 antibody and radiation therapy for head and neck 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 to the effect that treatment effect on the area where Telomelysin had been administered 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.

Meanwhile, regarding the above i) "Phase I sponsor-initiated clinical trial in combination with radiation therapy for esophageal cancer," the safety evaluation in the Phase I sponsor-initiated clinical trial was completed by the Data and Safety Monitoring Committee in September 2019. Further domestic development beyond the Phase II clinical trial for esophageal cancer will be led by Chugai.

In addition, 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 prior to application for approval from the Pharmaceuticals and Medical Devices

Agency (PMDA).

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. This test evaluates and observes the safety and secondary efficacy of the combination of Telomelysin and anti-PD-1 antibody, which are being clinically administered together for the first time.

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. The presentation reported that, as a result of administration to patients with stage 4 solid tumors, no significant side effects which would restrict administration occurred, and other marked side effects which could be presumably associated with Telomelysin were mild or medium fever, and that systemic partial responses (PR) were observed in 3 among 9 patients at a preliminary efficacy evaluation for secondary outcome measures.

Regarding the above iii) “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 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 protocol of this clinical trial was presented at a meeting of the American Society of Clinical Oncology (ASCO) held in Chicago, the U.S. in June 2019.

Regarding iv) Phase I/II clinical trial for HCC, the final stage of Phase I, including single and repeated dose administration, is being conducted with Pusan National University (South Korea) and National Taiwan University (Taiwan) as the clinical trial facilities.

In addition, the Company will be starting Phase II clinical trials in the US for head and neck cancer, in combination with an anti-PD-1 antibody and radiation therapy, so preparations are being made, such as creating protocols, for the start of the investigator-initiated clinical trial.

Furthermore, Jiangsu Hengrui Medicine Co., Ltd. (China), 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 is preparing to apply to the Chinese government (National Medical Products Administration: NMPA) to conduct clinical trials.

2) Other activities related to the pharmaceutical business

The Company started administration in the US for Phase I clinical trials in May 2015 for OBP-801, a histone deacetylase (HDAC) inhibitor licensed from Astellas Pharma Inc. in 2009, for patients with advanced solid tumors that show resistance to other forms of treatment. However, dose limiting toxicity was observed in cohort 3 and thus, at present, study enrollment of new patients was tentatively stopped, 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 a research group from the Ophthalmology Department of the Kyoto Prefectural University of Medicine and plans to conduct joint research with them.

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. In the future, 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 integration of pipeline products for effective utilization of management resources.

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 (oncolytic adenovirus immunotherapy)	Esophageal cancer In combination with radiation therapy	Japan	Phase I
		Various types of solid tumor In combination with anti-PD-1 antibody	Japan	Phase I
		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
		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 is continuing to consider clinical applications for circulating tumor cells (CTC) in the blood in the field of lung cancer with Juntendo University. Liquid Biotech USA, Inc. (the U.S.), to which rights were granted in the North American territory, has begun preparation for starting joint research with universities and research institutions in the U.S.

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