Non-consolidated Financial Results for the Nine Months Ended September 30, 2018 [Japanese GAAP]

November 2, 2018

Company name: Oncolys BioPharma Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4588
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Scheduled date of filing quarterly securities report: November 2, 2018
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, 2018 (January 1, 2018 to September 30, 2018)

(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, 2018	118	308.0	(915)	-	(899)	-	(901)	-
September 30, 2017	29	(37.6)	(768)	-	(776)	-	(779)	-

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2018	(79.31)	-
September 30, 2017	(77.81)	-

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of September 30, 2018	3,345	2,856	85.0
As of December 31, 2017	3,526	2,931	82.9

(Reference) Equity: As of September 30, 2018: ¥2,842 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	-	0.00	-		
Fiscal year ending December 31, 2018 (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, 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: Yes
2) Changes in accounting policies other than 1) above: No
3) Changes in accounting estimates: No
4) Retrospective restatement: No

Notes on changes in accounting policies

(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, 2018: 12,564,000 shares
December 31, 2017: 11,086,000 shares

2) Total number of treasury shares at the end of the period:
September 30, 2018: - shares
December 31, 2017: - shares

3) Average number of shares during the period:
Nine months ended September 30, 2018: 11,372,784 shares
Nine months ended September 30, 2017: 10,015,988 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

The Japanese economy during the nine months ended September 30, 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 friction between the U.S. and China caused by the U.S. Trump administration's policies and concerns over rising interest rates in the U.S.

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 nine months ended September 30, 2018, net sales were ¥118,422 thousand (¥29,027 thousand in the same period of the previous year), and operating loss was ¥915,408 thousand (operating loss of ¥768,416 thousand in the same period of the previous year). In addition, the Company recorded interest income of ¥15,442 thousand, foreign exchange gains of ¥2,941 thousand and other items as non-operating income, and interest expenses of ¥2,159 thousand as non-operating expenses. As a result, ordinary loss was ¥899,150 thousand (ordinary loss of ¥776,782 thousand in the same period of the previous year), and loss was ¥901,951 thousand (loss of ¥779,361 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 other revenues, and as a result, net sales were ¥113,988 thousand (net sales of ¥9,122 thousand in the same period of the previous year), and operating loss was ¥340,123 thousand (operating loss of ¥288,022 thousand in the same period of the previous year).

2) Diagnostic business

In the diagnostic business, in addition to sales of TelomeScan, a drug for detecting circulating tumor cells (CTCs) in blood, research-related contracted testing revenue was generated from academia, and as a result, net sales were ¥4,434 thousand (net sales of ¥19,904 thousand in the same period of the previous year), and operating loss was ¥126,824 thousand (operating loss of ¥83,485 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 ¥3,345,203 thousand (5.1% decline compared with the end of the previous fiscal year), owing partly to a decline in cash and deposits. Liabilities were ¥488,306 thousand (17.8% decline compared with the end of the previous fiscal year), owing partly to a decline in accounts payable – other. Net assets were ¥2,856,896 thousand (2.6% 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 September 30, 2018
Assets		
Current assets		
Cash and deposits	2,867,512	2,389,329
Accounts receivable - trade	88,736	27,987
Finished goods	11,807	15,263
Work in process	4,931	—
Supplies	1,842	1,728
Advance payments - other	12,645	—
Prepaid expenses	51,011	35,676
Accounts receivable - other	6,822	22,517
Consumption taxes receivable	26,116	21,697
Other	285	729
Total current assets	3,071,713	2,514,927
Non-current assets		
Property, plant and equipment		
Buildings	2,794	2,794
Accumulated depreciation	(2,794)	(2,794)
Buildings, net	—	—
Tools, furniture and fixtures	67,313	68,772
Accumulated depreciation	(64,807)	(66,013)
Tools, furniture and fixtures, net	2,506	2,759
Total property, plant and equipment	2,506	2,759
Investments and other assets		
Investment securities	400,194	685,403
Shares of subsidiaries and associates	10,173	101,153
Investments in capital	100	100
Long-term loans receivable from subsidiaries and associates	11,079	11,358
Lease and guarantee deposits	29,212	28,527
Long-term prepaid expenses	1,223	955
Other	19	19
Total investments and other assets	452,002	827,516
Total non-current assets	454,508	830,275
Total assets	3,526,222	3,345,203

(Thousand yen)

	As of December 31, 2017	As of September 30, 2018
Liabilities		
Current liabilities		
Short-term loans payable	93,336	83,336
Lease obligations	9,822	7,034
Accounts payable – other	88,740	34,857
Accrued expenses	10,959	11,483
Income taxes payable	32,826	19,586
Deposits received	3,351	6,715
Total current liabilities	239,035	163,012
Non-current liabilities		
Long-term loans payable	344,440	319,438
Lease obligations	7,140	2,057
Provision for retirement benefits	3,712	3,798
Total non-current liabilities	355,293	325,294
Total liabilities	594,328	488,306
Net assets		
Shareholders' equity		
Capital stock	5,802,444	6,203,996
Capital surplus		
Legal capital surplus	5,794,944	6,196,496
Total capital surpluses	5,794,944	6,196,496
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(8,660,016)	(9,561,968)
Total retained earnings	(8,660,016)	(9,561,968)
Total shareholders' equity	2,937,371	2,838,523
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	(15,786)	4,092
Total valuation and translation adjustments	(15,786)	4,092
Share acquisition rights	10,309	14,280
Total net assets	2,931,893	2,856,896
Total liabilities and net assets	3,526,222	3,345,203

(2) Quarterly Statements of Income

Nine Months Ended September 30

(Thousand yen)

	For the nine months ended September 30, 2017	For the nine months ended September 30, 2018
Net sales	29,027	118,422
Cost of sales	3,968	89,431
Gross profit	25,058	28,990
Selling, general and administrative expenses	793,475	944,399
Operating loss	(768,416)	(915,408)
Non-operating income		
Interest income	2,964	15,442
Dividend income	4	4
Foreign exchange gains	—	2,941
Other	29	30
Total non-operating income	2,997	18,418
Non-operating expenses		
Interest expenses	2,454	2,159
Foreign exchange losses	8,909	—
Total non-operating expenses	11,363	2,159
Ordinary loss	(776,782)	(899,150)
Loss before income taxes	(776,782)	(899,150)
Income taxes - current	2,578	2,801
Total income taxes	2,578	2,801
Loss	(779,361)	(901,951)

(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 July 18, 2018 to September 30, 2018, the Company received payments for the exercise of stock acquisition rights. As a result, capital stock and legal capital surplus each increased by ¥401,552 thousand during the nine months ended September 30, 2018, and at the end of the third quarter of the fiscal year under review, capital stock was ¥6,203,996 thousand and legal capital surplus was ¥6,196,496 thousand.

(Changes in accounting policies)

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

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

(Segment information, etc.)

[Segment information]

I. For nine months ended September 30, 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	9,122	19,904	29,027	—	29,027
Inter-segment net sales or transfers	—	—	—	—	—
Total	9,122	19,904	29,027	—	29,027
Segment loss	(288,022)	(83,485)	(371,507)	(396,909)	(768,416)

(Notes) 1. The adjustment to segment loss of negative ¥396,909 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 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.

3. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the nine months ended September 30, 2018 totaled ¥410,072 thousand, including ¥281,921 thousand for the pharmaceutical business, ¥103,061 thousand for the diagnostic business, and ¥25,089 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, 2018, 16 persons belonged to research and development departments, equivalent to 48.5% of the total number of employees.

(2) Research and development and business activities

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

(a) Pharmaceutical business

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

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

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

Regarding ii) "Phase I sponsor-initiated clinical trial in combination with radiation therapy for esophageal cancer" whose target population is the same as those for "investigator-initiated clinical study in combination with radiation therapy for esophageal cancer," in March 2018, the Data and Safety Monitoring Committee confirmed the safety of Telomelysin® in the low-dose administration patient cohort and the Company began to administer it to the higher-dose patient cohort. This trial is being conducted at Okayama University Hospital and National Cancer Center Hospital East, and the Company intends to administer it to up to 9 patients.

Additionally, in July 2018, the Company held a workshop with domestic esophageal cancer specialists and selected new sites for the Phase II clinical trial in order to transition to the Phase II clinical trial as soon as the Phase I clinical trial is completed. The Company has also been consulting with the Pharmaceuticals and Medical Devices Agency (PMDA) about the Phase II clinical trial. Furthermore, the Company established a cooperative structure with the Japan Esophageal Society and is steadily preparing to begin the Phase II clinical trial.

Regarding iii) "investigator-initiated clinical trial in combination with an anti-PD-1 antibody for various types of solid tumors" where combination with anti-PD-1 immune checkpoint inhibitor pembrolizumab is evaluated for various types of solid tumors centered on esophageal cancer, administration to patients began in December 2017 and in this trial, its safety, tolerability, etc. on patients with advanced or metastatic solid tumors will be evaluated and examined on up to 28 patients. In addition, at the American Society of Clinical Oncology (ASCO) meeting held in Chicago, the U.S. in June 2018, the protocol of this clinical trial was presented by the Department of Experimental Therapeutics, National Cancer Center Hospital East, which is leading this trial.

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

Regarding v) Phase I/II clinical trial for hepatocellular cancer, a study involving both single-dose and repeated administration to 16 patients was conducted with Pusan National University (South Korea) and National Taiwan University (Taiwan) as trial sites. The Company plans to complete the Phase I clinical trial in 2018.

In addition to the above, toward initiating investigator-initiated clinical trials in combination with an anti-PD-1 antibody for esophageal cancers, centered on Cornell University in the U.S., the Company submitted a clinical trial (Phase II) application to the U.S. Food and Drug Administration on August 30, 2018. Furthermore, Jiangsu Hengrui Medicine Co., Ltd. (China), a licensee of research, development, manufacturing, and sales rights of Telomelysin® in China, is preparing to apply to the Chinese government (CFDA) to conduct clinical trials.

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

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

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. 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.

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, including 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. 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
		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, the Company and Juntendo University is continuing joint research in the field of circulating tumor cells (CTC) in the blood from November 2017, 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, the Company entered into a joint research agreement with Shimane University regarding the field of female-specific cancer under which the CTC inspection system. The Company aims to commercialize a new cancer detection system where cervical cancer examinations can be possible with less invasive blood sampling through detection of genes of human papillomavirus from CTCs in cervical cancer patients.

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