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 Six Months Ended June 30, 2023 [Japanese GAAP]

August 4, 2023

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
Email: oncolys_information@oncolys.com
Scheduled date of filing quarterly securities report: August 4, 2023
Scheduled date of commencing dividend payments: —
Availability of supplementary briefing material on quarterly financial results: No
Schedule of quarterly financial results briefing session: Scheduled (for analysts)

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

1. Financial Results for the Six Months Ended June 30, 2023 (January 1, 2023 to June 30, 2023)

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

	Net sales		Operating profit		Ordinary profit		Profit	
Six months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
June 30, 2023	63	(85.2)	(900)	–	(867)	–	(868)	–
June 30, 2022	426	–	(658)	–	(590)	–	(570)	–

(Note) The Company has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020), etc. from the beginning of the three months ended March 31, 2022. As the application of the accounting standard etc. has a significant effect on net sales, the Company does not present the percentage of change in net sales for the six months ended June 30, 2022 from the previous corresponding period.

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
June 30, 2023	(50.16)	–
June 30, 2022	(32.92)	–

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of June 30, 2023	1,866	1,290	68.7
As of December 31, 2022	2,650	2,159	81.2

(Reference) Equity: As of June 30, 2023: ¥1,282 million
As of December 31, 2022: ¥2,151 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, 2022	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2023	–	0.00			
Fiscal year ending December 31, 2023 (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, 2023 (January 1, 2023 to December 31, 2023)

Financial results forecast is not disclosed due to the difficulty of making reasonable estimates. For details, 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 2 of the supplementary material.

*** 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):
June 30, 2023: 17,405,200 shares
December 31, 2022: 17,405,200 shares

2) Total number of treasury shares at the end of the period:
June 30, 2023: 87,738 shares
December 31, 2022: 82,238 shares

3) Average number of shares during the period:
Six months ended June 30, 2023: 17,318,729 shares
Six months ended June 30, 2022: 17,330,403 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 2 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

During the six months ended June 30, 2023, the Japanese economy saw the Nikkei Stock Average hit a post-bubble high. According to the Bank of Japan's Tankan survey for June released in July, a wide range of companies were passing on increased raw material costs to prices, and the weakened yen as a tailwind for businesses targeting foreign visitors to Japan and higher operating profit for export businesses led to a rapid improvement in business confidence, especially among large companies. On the other hand, the outlook of the global economy remained uncertain as there was lingering risk of a slowdown due to monetary tightening by central banks of major countries including the Bank of England in the U.K., which continued to raise interest rates to counter inflation, although the U.S. Federal Reserve Board (FRB) decided to keep interest rates unchanged.

Under these circumstances, the Company has been pursuing a vision of "Providing new options for future cancer treatments, and leaving our footprint in the history of cancer treatment," thus striving to increase managerial efficiency and actively expand research, development, and licensing activities.

In particular, the Company is promoting research, development, and business activities with the aim of "virus drug discovery" within the business fields of "virotherapy for cancer" and "drugs for the treatment of serious viral infectious diseases," with a focus on Telomelysin (OBP-301), a virotherapy for cancer, and OBP-2011 for the treatment of COVID-19. In addition, concerning OBP-601 (censavudine), a nucleoside reverse transcriptase inhibitor, Transposon Therapeutics, Inc. (hereinafter "Transposon") is conducting multiple clinical trials in Europe and the U.S. entirely at its own expense based on a license agreement.

For details of the Company's activities, please refer to "3. Supplemental Information (1) Research and development activities."

For the six months ended June 30, 2023, net sales were ¥63,038 thousand (net sales of ¥426,152 thousand in the same period of the previous fiscal year), and operating loss was ¥900,989 thousand (operating loss of ¥658,898 thousand in the same period of the previous fiscal year). In addition, the Company recorded interest income of ¥533 thousand and foreign exchange gains of ¥35,051 thousand as non-operating income, and interest expenses of ¥1,781 thousand and amortization of restricted stock remuneration of ¥435 thousand as non-operating expenses. As a result, ordinary loss was ¥867,441 thousand (ordinary loss of ¥590,514 thousand in the same period of the previous fiscal year), and net loss was ¥868,762 thousand (net loss of ¥570,569 thousand in the same period of the previous fiscal year).

(2) Explanation of Financial Position

Assets at the end of the second quarter of the fiscal year under review were ¥1,866,628 thousand (29.6% decrease compared with the end of the previous fiscal year), primarily due to a decrease in cash and deposits. Liabilities were ¥576,121 thousand (17.2% increase compared with the end of the previous fiscal year), mainly on account of an increase in accounts payable - other. Net assets were ¥1,290,506 thousand (40.2% decrease compared with the end of the previous fiscal year), due to net loss incurred, as well as other factors.

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

The Company still has a small stable revenue base, and our financial results fluctuate greatly depending on contractual lump-sum payments from the conclusion of new contracts and milestone revenue payments generated from licensees achieving events. There is also a risk that disclosing our full-year earnings forecast for the fiscal year ending December 31, 2023 could affect our negotiations on economic terms for the Telomelysin domestic distribution partnership agreement planned for 2023, as well as our negotiations on terms for the establishment of a collaborative research system for Telomelysin with a major pharmaceutical company in the United States that markets an immune checkpoint inhibitor.

For these reasons, we believe that it is difficult to calculate an appropriate and reasonable figure for the earnings forecast at this time due to the many undetermined factors that will affect our business performance, and therefore, we refrain from disclosing the forecast.

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousand yen)

	As of December 31, 2022	As of June 30, 2023
Assets		
Current assets		
Cash and deposits	1,711,280	1,335,419
Finished goods	8,434	6,124
Work in process	12,666	–
Supplies	3,149	2,828
Advance payments – other	506,316	313,793
Prepaid expenses	47,970	42,186
Short-term loans receivable from subsidiaries and associates	39,813	14,499
Accounts receivable – other	174,310	53,524
Income taxes refund receivable	28,299	–
Consumption taxes receivable	75,982	21,463
Advances paid	29	–
Other	501	8
Total current assets	2,608,754	1,789,848
Non-current assets		
Property, plant and equipment		
Buildings	2,794	4,794
Accumulated depreciation	(2,794)	(2,794)
Buildings, net	–	2,000
Tools, furniture and fixtures	65,939	68,791
Accumulated depreciation	(65,939)	(66,080)
Tools, furniture and fixtures, net	–	2,711
Total property, plant and equipment	–	4,711
Investments and other assets		
Shares of subsidiaries and associates	20,936	20,936
Investments in capital	100	100
Long-term loans receivable from subsidiaries and associates	–	28,998
Lease and guarantee deposits	21,149	21,083
Long-term prepaid expenses	–	947
Other	19	4
Total investments and other assets	42,204	72,068
Total non-current assets	42,204	76,779
Total assets	2,650,959	1,866,628

(Thousand yen)

	As of December 31, 2022	As of June 30, 2023
Liabilities		
Current liabilities		
Short-term loans payable	227,776	236,110
Lease obligations	3,581	3,622
Accounts payable – other	60,858	96,104
Accrued expenses	17,099	14,449
Income taxes payable	2,931	10,887
Deposits received	9,392	7,980
Total current liabilities	321,639	369,153
Non-current liabilities		
Long-term loans payable	155,544	194,436
Lease obligations	6,758	4,936
Provision for retirement benefits	7,748	7,595
Total non-current liabilities	170,051	206,967
Total liabilities	491,690	576,121
Net assets		
Shareholders' equity		
Capital stock	3,000,000	3,000,000
Capital surplus		
Legal capital surplus	586,425	586,425
Total capital surpluses	586,425	586,425
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(1,434,694)	(2,303,457)
Total retained earnings	(1,434,694)	(2,303,457)
Treasury shares	(142)	(142)
Total shareholders' equity	2,151,589	1,282,826
Share acquisition rights	7,680	7,680
Total net assets	2,159,269	1,290,506
Total liabilities and net assets	2,650,959	1,866,628

(2) Quarterly Statements of Income

Six Months Ended June 30

(Thousand yen)

	For the six months ended June 30, 2022	For the six months ended June 30, 2023
Net sales	426,152	63,038
Cost of sales	186,697	32,433
Gross profit	239,454	30,604
Selling, general and administrative expenses	898,353	931,594
Operating loss	(658,898)	(900,989)
Non-operating income		
Interest income	284	533
Dividend income	–	3
Foreign exchange gains	84,344	35,051
Other	12	177
Total non-operating income	84,641	35,765
Non-operating expenses		
Interest expenses	1,937	1,781
Amortization of restricted stock remuneration	14,289	435
Share issuance costs	30	–
Total non-operating expenses	16,257	2,217
Ordinary loss	(590,514)	(867,441)
Extraordinary income		
Gain on sale of bonds	21,406	–
Gain on sale of non-current assets	–	136
Total extraordinary income	21,406	136
Loss before income taxes	(569,108)	(867,305)
Income taxes - current	1,461	1,457
Total income taxes	1,461	1,457
Loss	(570,569)	(868,762)

(3) Quarterly Statements of Cash Flows

(Thousand yen)

	For the six months ended June 30, 2022	For the six months ended June 30, 2023
Cash flows from operating activities		
Loss before income taxes	(569,108)	(867,305)
Depreciation	155	141
Amortization of restricted stock remuneration	14,289	435
Gain on sale of bonds	(21,406)	–
Share-based remuneration expenses	41,705	5,488
Increase (decrease) in provision for retirement benefits	1,792	(153)
Interest and dividend income	(287)	(536)
Interest expenses	1,937	1,781
Foreign exchange losses (gains)	(82,550)	(34,696)
Decrease (increase) in notes and accounts receivable – trade	321,697	–
Decrease (increase) in inventories	251	15,297
Decrease (increase) in prepaid expenses	(6,679)	(1,083)
Decrease (increase) in accounts receivable – other	(77,824)	149,396
Decrease (increase) in consumption taxes refund receivable	(21,868)	54,519
Decrease (increase) in advance payments – other	(68,762)	192,523
Increase (decrease) in accounts payable – other	(49,980)	31,576
Increase (decrease) in contract liabilities	(151,697)	–
Other, net	(51,383)	5,761
Subtotal	(719,719)	(446,855)
Interest and dividend income received	154	243
Interest expenses paid	(2,189)	(2,017)
Income taxes paid	(728)	(2,923)
Net cash provided by (used in) operating activities	(722,482)	(451,552)
Cash flows from investing activities		
Proceeds from sale of bonds	21,406	–
Purchase of property, plant and equipment	(635)	(951)
Proceeds from sale of property, plant and equipment	–	136
Proceeds from refund of lease and guarantee deposits	71	66
Net cash provided by (used in) investing activities	20,841	(748)
Cash flows from financing activities		
Proceeds from long-term loans payable	100,000	100,000
Repayments of long-term loans payable	(72,220)	(52,774)
Net increase (decrease) in short-term loans payable	2,786	–
Repayments of lease obligations	(907)	(1,780)
Purchase of treasury shares	(28)	–
Other payments	(30)	–
Net cash provided by (used in) financing activities	29,599	45,445
Effect of exchange rate change on cash and cash equivalents	76,061	30,994
Net increase (decrease) in cash and cash equivalents	(595,979)	(375,860)
Cash and cash equivalents at beginning of period	3,209,635	1,466,201
Cash and cash equivalents at end of period	2,613,656	1,090,340

(4) 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 the six months ended June 30, 2022

The information is omitted, as the Company consists of a single segment of the drug discovery business.

II. For the six months ended June 30, 2023

The information is omitted, as the Company consists of a single segment of the drug discovery business.

(Revenue recognition)

Disaggregation of revenue from contracts with customers

(Thousand yen)

	For the six months ended June 30, 2022	For the six months ended June 30, 2023
Goods / Services transferred at a point in time	62,075	63,038
Goods / Services transferred over time	364,076	–
Revenue from contracts with customers	426,152	63,038
Revenue from other sources	–	–
Net sales to outside customers	426,152	63,038

(Significant subsequent events)

1. Issuance of 19th series share acquisition rights (with exercise price adjustment clause) through third-party allotment

The Company resolved, at the Board of Directors meeting held on July 7, 2023, to issue share acquisition rights (with exercise price adjustment clause) (hereinafter, the "Share Acquisition Rights") through third-party allotment by designating SMBC Nikko Securities Inc. (hereinafter, "SMBC Nikko Securities") as a scheduled allottee, and confirmed the completion of the payment of the total issue price on July 24, 2023.

Outline of the 19th series share acquisition rights (with exercise price adjustment clause) through third-party allotment

Date of allotment	July 24, 2023
Number of share acquisition rights issued	36,400 units
Class and number of shares to be issued upon exercise of stock acquisition rights	100 shares of the Company's common stock per share acquisition right
Issue price	610 yen per Share Acquisition Right (Total amount: 21,106,000 yen)
Number of potential shares resulting from the issuance	Number of potential shares: 3,460,000 shares There is no upper limit of exercise price. While the lower limit of exercise price is 313 yen, the number of potential shares even at the lower limit of exercise price is 3,460,000 shares.
Amount of funds to be procured	2,175,606,000 yen (estimated net proceeds) (Note)

<table>
<tr><td>Exercise price and conditions for adjustment of exercise price</td><td>Initial exercise price: 625 yen
The exercise price is adjusted, on the effective date of each exercise request of the Share Acquisition Rights, to the amount equivalent to 91% of the closing price of the Company's common stock in regular trading on the Tokyo Stock Exchange, Inc. on the trading date immediately preceding the said effective date. However, if the adjusted exercise price falls below the lower limit of exercise price, the lower limit of exercise price shall be set as the adjusted exercise price.</td></tr>
<tr><td>Capital stock and legal capital surplus to be increased where shares are issued upon the exercise of share acquisition rights</td><td>Where shares of common stock are issued upon the exercise of the Share Acquisition Rights, the amount of capital stock to be increased shall be one half of the maximum increase amount of capital stock, as calculated in accordance with the provisions of Article 17 of the Regulations on Corporate Accounting, with any fraction less than one yen resulting from the calculation being rounded up to the nearest one yen. The amount of legal capital surplus to be increased is the amount obtained by subtracting the said amount of capital stock to be increased from the maximum amount of increase of capital stock.</td></tr>
<tr><td>Method of offering or allotment</td><td>Third-party allotment</td></tr>
<tr><td>Allottee</td><td>SMBC Nikko Securities</td></tr>
<tr><td>Exercisable period</td><td>From July 25, 2023 to July 31, 2025</td></tr>
<tr><td>Use of funds</td><td><table><tr><th>Specific use</th><th>Amount (thousand yen)</th></tr><tr><td>(i) Costs for manufacture, sale and distribution of Telomelysin</td><td>1,127,000</td></tr><tr><td>(ii) Working capital mainly for establishing manufacturing and sales system for Telomelysin and its maintenance</td><td>1,048,606</td></tr><tr><td>Total</td><td>2,175,606</td></tr></table></td></tr>
<tr><td>Other</td><td>The Company executed an agreement on purchase of the Share Acquisition Rights (hereinafter the "Share Acquisition Rights Purchase Agreement") with SMBC Nikko Securities after the notification pursuant to the Financial Instruments and Exchange Act took effect. The Share Acquisition Rights Purchase Agreement provides that SMBC Nikko Securities shall not be allowed to transfer the Share Acquisition Rights to any third party other than the Company without prior consent of the Company.</td></tr>
</table>

(Note) The amount of funds to be procured is the sum of the total amount to be paid in for the Share Acquisition Rights plus the total amount of property to be contributed upon exercise of the Share Acquisition Rights, less an estimated amount of expenses related to the issuance of the Share Acquisition Rights. Note that the total amount of property to be contributed upon exercise of the Share Acquisition Rights is the amount assuming that all the Share Acquisition Rights will be exercised at the initial exercise price. Accordingly, if the exercise price of the Share Acquisition Rights is revised or adjusted, the amount of funds procured will increase or decrease. Furthermore, the amount of funds procured will decrease if the Share Acquisition Rights are not exercised within the exercisable period or if the Company cancels the Share Acquisition Rights it acquired.

2. Capital increase through exercise of share acquisition rights
During the period starting on July 25, 2023 and ending on July 31, 2023, a portion of the Share Acquisition Rights was exercised as follows:

(1) Class and number of shares issued	26,600 shares of common stock
(2) Number of units of share acquisition rights exercised	266 units
(3) Total amount exercised	12,955 thousand yen
(4) Amount of increase in capital stock	6,477 thousand yen
(5) Amount of increase in legal capital surplus	6,477 thousand yen

3. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the six months ended June 30, 2023 totaled ¥636,952 thousand for the drug discovery business. The status of research and development activities during the six month ended June 30, 2023 is as follows.

(1) Research and development structure

As of June 30, 2023, 20 persons belonged to research and development department, accounting for 50.0% 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.

1) Activities related to Telomelysin (OBP-301) (International Nonproprietary Name: suratadenoturev) virotherapy for cancer

The Company is conducting a "Phase II clinical trial in combination with radiation therapy for esophageal cancer" for Telomelysin, for which the Ministry of Health, Labour and Welfare has granted "SAKIGAKE designation" for regenerative medicine products in Japan. We have already completed enrollment of patients and entered the stage of following up on the prognosis of all cases, with plans to submit a new drug application in Japan in 2024. We have also made progress in viral production development on a commercial scale and advance discussions are underway with the PMDA. Furthermore, we have begun preparing to establish our own manufacturing and sales system, and we are proceeding with due diligence and negotiations on terms and conditions for an alliance with companies that are candidates to be our marketing partners. Meanwhile, with regard to overseas development, we have presented clinical trial protocols to a major foreign pharmaceutical company that markets immune checkpoint inhibitors in order to establish a joint development system for Telomelysin in the Unites States, and have obtained agreement on such protocols.

Currently, Telomelysin is undergoing the following three clinical trials in Japan and overseas, including the clinical trial for which enrollment has been completed:

i) Phase II clinical trial in combination with radiation therapy for esophageal cancer;
ii) Phase II investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for gastric cancer/gastroesophageal junction cancer; and
iii) Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer

Regarding the above i) "Phase II clinical trial in combination with radiation therapy for esophageal cancer," trials are ongoing based on the "SAKIGAKE designation" of April 2019 at 17 clinical trial sites around Japan, and we confirmed that the target number of patients for this clinical trial was reached in December 2022. We are currently conducting a follow-up study to determine the prognosis of cases. In June 2023, we held a technical committee meeting for Phase II clinical trial, confirmed the progress status of the trial, and reported on the policy going forward. The results for this trial are expected to be available in October 2023. To date, there have been no reports of safety problems that necessitate the termination of the trials. In parallel with this clinical trial, we have started preliminary consultations with PMDA regarding non-clinical trials, clinical trials, manufacturing, etc., toward filing for approval.

The Company is currently moving forward on manufacturing development for commercial production at Belgium's Henogen SA with a view to submitting a new drug application for Telomelysin. We plan to begin process validation in November 2023 and commercial manufacturing in 2024, when the new drug application will be submitted.

In addition, we are preparing to establish a logistics system in partnership with a company that will serve as the manufacturing base in Japan so that, after Telomelysin is formulated by Henogen, it can be imported into Japan and transported smoothly to medical institutions, keeping the GMP manufacturing system effectively maintained, and we plan to conclude an agreement in September 2023. In June 2023, we signed a contract with Eurofins Analytical Science Laboratories to begin the validation of quality tests necessary to make a final determination for shipment of Telomelysin. Furthermore, to ensure efficient sales in Japan, we are undertaking negotiations to form a marketing partnership with pharmaceutical companies and are aiming to conclude an agreement by the end of 2023.

Regarding the above ii) "Phase II investigator-initiated clinical trial in combination with pembrolizumab, an anti-

PD-1 antibody, for gastric cancer/gastroesophageal junction cancer," administration began in May 2019 led by Cornell University in the U.S. with the goal of evaluating the efficacy and safety of Telomelysin and pembrolizumab, and was performed for the most advanced patients who have been treated in the past. Long-term survival has been confirmed in 3 of the 16 patients enrolled so far. As this result was deemed to satisfy the standard set for efficacy in the trial, we decided to terminate enrollment in this clinical trial at the end of 2022 ahead of schedule without waiting for the enrollment of 18 patients, which was the initial target. In addition, the interim analysis results of this clinical trial were presented by Dr. Manish A. Shah of Cornell University in the U. S. at an annual meeting of the American Society of Clinical Oncology (ASCO June 2023). Based on the results of this trial, we are currently planning the next step of clinical trials with Cornell University, and plan to establish a joint development system in September 2023, including overseas pharmaceutical companies that market immune checkpoint inhibitors.

Regarding the above iii) "Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer," NRG Oncology, an authoritative cancer research organization in the U.S., has been leading the trial, and administration began in December 2021 with the purpose of investigating the safety and efficacy of using Telomelysin in combination with chemoradiotherapy. This clinical trial is currently being conducted in six facilities within the U.S., and the enrollment of all six patients for the first stage has been completed. Thus far, there have been no reports of problematic side-effects. Telomelysin has been designated as an orphan drug for esophageal cancer in the U.S., and this clinical trial is being conducted on that basis. Therefore, the Company will be able to receive preferential treatment in the form of grants and tax credits for clinical research expenses. Furthermore, first-mover rights protection will be granted for seven years after the approval of Telomelysin in the U.S., during which market exclusivity is to be granted.

2) Activities related to OBP-601 (censavudine), a nucleoside reverse transcriptase inhibitor

The Company licensed in OBP-601 from Yale University in 2006. From 2010 to 2014, it was licensed to Bristol-Myers Squibb Co. (hereinafter "BMS"), which conducted Phase II clinical trials as a treatment drug for HIV infection. The results demonstrated the non-inferiority of OBP-601 to existing drugs. During the same period, BMS also obtained numerous clinical safety data for long-term OBP-601 toxicity studies and oncogenicity studies, but due to BMS's change of strategy, namely withdrawing from the HIV field, the license agreement was terminated.

Subsequently, results of a study by Brown University of the U.S. confirmed that nucleic acid-based reverse transcriptase inhibitors (NRTIs) of HIV suppress the aberrant expression of a retrotransposons and that OBP-601, which has the same effect, has high brain translocability and strongly suppresses the production of a retrotransposon called LINE-1. In June 2020, we concluded a new licensing agreement worth more than $300 million worldwide with Transposon which had been planning to apply OBP-601 to intractable neurological diseases focusing on this mechanism. In November of the same year, Transposon achieved its first milestone.

Transposon is currently conducting two double-blind Phase IIa clinical trials that make use of placebos at numerous facilities, both in Europe and the U.S. One covers progressive supranuclear palsy (PSP), while the other is on amyotrophic lateral sclerosis (ALS), with the abnormal expression of the enzyme C9 ORF, and frontotemporal degeneration (FTD). In addition, in July 2023, administration began under a single-arm Phase IIa clinical trial in Europe for the treatment of Aicardi-Goutières Syndrome (AGS).

Administration to the first patient under the Phase IIa clinical trial for PSP began in November 2021, and enrollment of the target number of patients was concluded in August 2022. Although we have received a report from Transposon on the results of the interim analysis, the details of the analysis are yet to be disclosed at this time due to Transposon's request. To date, there have been no reports of safety problems that necessitate the termination of the trials.

In addition, administration under the clinical trial for C9-ALS and FTD began in January 2022, and target enrollment was concluded in March 2023. We are now conducting a long-term follow-up study on the enrolled patients. To date, there have been no reports of safety problems that necessitate the termination of the trials.

Furthermore, in July 2023, Transposon started administration under a new Phase IIa clinical trial for AGS, a genetic disorder that causes microcephaly and severe mental retardation, after receiving regulatory approval in Europe. These clinical trials on OBP-601 are proceeding entirely at Transposon's expense.

Transposon is a company that was established with the purpose of developing OBP-601. The Company therefore believes that the risk of Transposon suspending the development of OBP-601 due to a change in strategy is low.

3) Activities related to OBP-2011 for the treatment of COVID-19

Based on experimental outcomes, the Company assumes that OBP-2011 inhibits nucleocapsids, although the specific mechanism has not been clarified yet at this stage. It is speculated that OBP-2011 has a new mechanism that differs from the main mechanisms of polymerase and protease inhibition already approved for the treatment of coronaviruses, and data indicated that its effectiveness is not influenced by such factors as virus mutation. However, it has become necessary to revise the development policy as the hurdle has been raised for obtaining approval for our proposed COVID-19 treatment, at the same time as changes have emerged in the external environment, such as the reduced urgency due to the launch of multiple therapeutic drugs for COVID-19 to the market, and the concentration of management resources on Telomelysin, for which we aim to apply for approval in 2024. Going forward, the Company will proceed with clarifying the detailed mechanism of action for OBP-2011 by conducting collaborative research with Kagoshima University and the National Institute of Infectious Diseases and will consider new indications for RNA viruses other than coronaviruses, maintaining a framework that can respond to new pandemics.

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

OBP-702 is a second-generation virotherapeutic drug with two anti-tumor effects, combining the "oncogene therapy" that carries the powerful cancer suppressor gene p53 in the vector with the "oncolytic functions" of Telomelysin. A research group led by Professor Toshiyoshi Fujiwara of the Department of Gastroenterological Surgery, Transplant, and Surgical Oncology of Okayama University is conducting non-clinical trials on OBP-702, which was adopted as a grant program by the Japan Agency for Medical Research and Development (AMED). In particular, an experiment on gemcitabine-resistant pancreatic cancer cell lines using mouse models, OBP-702, used in combination with PD-L1 antibodies, exhibited stronger anti-tumor effects alone. It has also been shown to have a lethal effect on cancer associated fibroblasts (CAF), which are problematic in cancer therapy. It is expected that OBP-702 will be developed as a new treatment method for pancreatic cancer and other refractory cancers that are considered to be difficult to treat due to CAF. Development of OBP-702 will continue within the scope of the grant in order to concentrating management resources on Telomelysin, which we aim to submit for approval in 2024.

5) Activities related to TelomeScan (OBP-401), a cancer detection drug

Regarding TelomeScan, the Company set up a "Collaborative Research Program on Minimally Invasive Cancer Detection Method Using TelomeScan," in June 2021, with Juntendo University, aimed at establishing a platform for automated detection of live Circulating Tumor Cells (CTC) within the blood of cancer patients. However, the development with Juntendo University has been delayed due to the time required to acquire images compared to initial plans, given the large number of images that need to be acquired for AI image learning.

6) Activities related to OBP-801, HDAC inhibitor

Regarding OBP-801, a histone deacetylase (HDAC) inhibitor licensed from Astellas Pharma Inc. in 2009, dose limiting toxicity (DLT) was observed in Phase I clinical trials targeting solid body cancers in the U.S., making it impossible to escalate the dosage to the presumed effective dose. Therefore, development in the field of cancer has been suspended.

On the other hand, research for application to glaucoma surgery has been carried out at the Department of Ophthalmology of Kyoto Prefectural University of Medicine in the ophthalmic field, which is a new area of indication for OBP-801, revealing that the drug suppresses fibrosis after filtering bleb formation from glaucoma surgery. The research results were presented at a meeting of the Japanese Ophthalmological Society in April 2023 and at an annual meeting of the Association for Research in Vision and Ophthalmology (ARVO) held in New Orleans, Louisiana in the U.S. Going forward, there is hope for development in the form of eye drops.

The development status of pipeline products is as follows.

Product	Indication	Combination therapy	Development region	Development stage
Telomelysin (OBP-301) (Suratadenoturev)	Esophageal cancer	Radiation therapy	Japan	Phase II (Enrollment complete)
		Chemoradiotherapy	U.S.	Phase I
		Anti-PD-1 antibody pembrolizumab	Japan	Phase I (Enrollment complete)
	Gastric/ gastroesophageal junction cancer	Anti-PD-1 antibody pembrolizumab	U.S.	Phase II (Enrollment complete)
	Hepatocellular cancer (HCC)	Anti-PD-L1 antibody atezolizumab Molecular targeting drug	Japan	Phase I (complete)
		Monotherapy	South Korea and Taiwan	Phase I (complete)
OBP-601 (censavudine)	Progressive supranuclear palsy (PSP)	Monotherapy	U.S.	Phase IIa (Enrollment complete)
	Amyotrophic lateral sclerosis (C9-ALS) / frontotemporal degeneration (FTD)	Monotherapy	U.S. and Europe	Phase IIa (Enrollment complete)
	Aicardi-Goutières Syndrome (AGS)	Monotherapy	Europe	Phase IIa
OBP-2011	Novel coronavirus infection (COVID-19)	TBD	Japan	Pre-clinical
OBP-702	Solid tumor	Anti-PD-(L)1 antibody (expected)	Japan	Pre-clinical
TelomeScan (OBP-401)	Solid tumor	—	Japan	Clinical research
OBP-801	Suppression of filtering bleb fibrosis after glaucoma surgery	Monotherapy	Japan	Pre-clinical