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, 2024 [Japanese GAAP]

August 9, 2024

Company name: Oncolys BioPharma Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4588
URL: https://www.oncolys.com
Representative: Yasuo Urata, President & CEO
Contact: Kohei Hata, Executive Officer
Email: oncolys_information@oncolys.com
Scheduled date of filing semi-annual securities report: August 9, 2024
Scheduled date of commencing dividend payments: —
Availability of supplementary briefing material on financial results: No
Schedule of 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, 2024 (January 1, 2024 to June 30, 2024)

(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, 2024	31	(50.2)	(793)	–	(752)	–	(754)	–
June 30, 2023	63	(85.2)	(900)	–	(867)	–	(868)	–

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
June 30, 2024	(36.96)	–
June 30, 2023	(50.16)	–

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of June 30, 2024	1,885	1,417	74.7
As of December 31, 2023	2,040	1,474	71.5

(Reference) Equity: As of June 30, 2024: ¥1,409 million
As of December 31, 2023: ¥1,459 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, 2023	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2024	–	0.00			
Fiscal year ending December 31, 2024 (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, 2024 (January 1, 2024 to December 31, 2024)

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 semi-annual 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, 2024: 20,961,600 shares
December 31, 2023: 17,405,200 shares

2) Total number of treasury shares at the end of the period:
June 30, 2024: 92,738 shares
December 31, 2023: 82,238 shares

3) Average number of shares during the period:
Six months ended June 30, 2024: 20,421,423 shares
Six months ended June 30, 2023: 17,318,729 shares

* These semi-annual financial results are outside the scope of 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, 2024, the Japanese economy showed signs of improvement, with a positive outlook in the Bank of Japan's Tankan survey for June 2024 on the backdrop of the progress of passing costs on prices mainly at major companies and a recovery in production of semiconductors. Meanwhile, as the yen's depreciation continues, increased raw material costs and a higher-than-expected price hike have posed the risk of undermining the effects of economic improvement through the historic wage increases in the spring of 2024. Furthermore, risk factors in the global economy have prolonged, such as Russia's invasion of Ukraine and the conflict in Israel, in addition to the political factors, such as trends in the U.S. presidential election and a breakthrough of right-wing groups in Europe. The volatile situation of the overseas economy seems likely to continue, as manifested by less consumption due to high interest rates to curb inflation and other factors.

Under these circumstances, the Company has been pursuing a vision of "Providing new options to future cancer treatments, and leaving our footprint in the history of cancer treatment through those achievements." In particular, the Company is promoting research, development, and business activities with a focus on Telomelysin (OBP-301), a virotherapy for cancer. In addition, concerning LINE-1 inhibitor OBP-601 (censavudine), Transposon Therapeutics, Inc. (hereinafter "Transposon") is conducting clinical trials at its own expense based on a license agreement and proceeding with business activities.

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, 2024, the Company recorded net sales of ¥31,384 thousand (net sales of ¥63,038 thousand in the same period of the previous fiscal year), and operating loss was ¥793,371 thousand (operating loss of ¥900,989 thousand in the same period of the previous fiscal year). In addition, the Company recorded interest income of ¥1,047 thousand and foreign exchange gains of ¥48,518 thousand as non-operating income, and interest expenses of ¥2,185 thousand, amortization of restricted stock remuneration of ¥2,183 thousand, share acquisition rights issuance costs of ¥2,310 thousand, and share issuance costs of ¥2,466 thousand as non-operating expenses, resulting in ordinary loss of ¥752,997 thousand (ordinary loss of ¥867,441 thousand in the same period of the previous fiscal year). As a result, loss was ¥754,868 thousand (net loss of ¥868,762 thousand in the same period of the previous fiscal year).

(2) Explanation of Financial Position

Assets at the end of the semi-annual period of the fiscal year under review were ¥1,885,725 thousand (7.6% decrease compared with the end of the previous fiscal year), owing partly to a decrease in cash and deposits. Liabilities were ¥468,723 thousand (17.3% decrease compared with the end of the previous fiscal year), owing partly to a decrease in accounts payable - other. Net assets were ¥1,417,002 thousand (3.9% decrease compared with the end of the previous fiscal year), owing partly to net loss.

(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 the presence or absence of milestone revenue payments generated from our domestic distribution partnership agreement for Telomelysin, achieving the development event of LINE-1 inhibitor OBP-601, for which we have a license agreement with Transposon, and that company's IPO, or M&A and other corporate action that generates milestone revenue payments.

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. Semi-annual Financial Statements and Primary Notes

(1) Semi-annual Balance Sheets

(Thousand yen)

	As of December 31, 2023	As of June 30, 2024
Assets		
Current assets		
Cash and deposits	1,532,844	1,117,538
Accounts receivable - trade	–	32,206
Supplies	5,342	4,278
Advance payments – other	282,602	389,727
Prepaid expenses	33,338	68,396
Accounts receivable – other	51,781	135,950
Consumption taxes receivable	49,964	21,983
Other	9	–
Total current assets	1,955,883	1,770,082
Non-current assets		
Property, plant and equipment		
Buildings	3,128	3,128
Accumulated depreciation	(3,128)	(3,128)
Buildings, net	–	–
Machinery and equipment	924	924
Accumulated depreciation	(924)	(924)
Machinery and equipment, net	–	–
Tools, furniture and fixtures	66,967	66,967
Accumulated depreciation	(66,967)	(66,967)
Tools, furniture and fixtures, net	–	–
Total property, plant and equipment	–	–
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	42,549	48,309
Lease and guarantee deposits	20,990	22,174
Long-term prepaid expenses	135	24,119
Other	4	4
Total investments and other assets	84,714	115,643
Total non-current assets	84,714	115,643
Total assets	2,040,598	1,885,725

(Thousand yen)

	As of December 31, 2023	As of June 30, 2024
Liabilities		
Current liabilities		
Short-term loans payable	127,776	150,000
Lease obligations	7,565	5,909
Accounts payable – other	193,354	48,528
Accrued expenses	19,119	21,076
Income taxes payable	18,844	16,326
Deposits received	11,870	9,959
Total current liabilities	378,531	251,799
Non-current liabilities		
Long-term loans payable	161,100	194,436
Lease obligations	18,729	15,456
Provision for retirement benefits	8,140	7,030
Total non-current liabilities	187,969	216,923
Total liabilities	566,500	468,723
Net assets		
Shareholders' equity		
Capital stock	3,623,165	3,975,601
Capital surplus		
Legal capital surplus	1,209,590	1,561,930
Total capital surpluses	1,209,590	1,561,930
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(3,373,199)	(4,128,068)
Total retained earnings	(3,373,199)	(4,128,068)
Treasury shares	(142)	(142)
Total shareholders' equity	1,459,413	1,409,322
Share acquisition rights	14,683	7,680
Total net assets	1,474,097	1,417,002
Total liabilities and net assets	2,040,598	1,885,725

(2) Semi-annual Statements of Income

(Thousand yen)

	For the six months ended June 30, 2023	For the six months ended June 30, 2024
Net sales	63,038	31,384
Cost of sales	32,433	–
Gross profit	30,604	31,384
Selling, general and administrative expenses	* 931,594	* 824,755
Operating loss	(900,989)	(793,371)
Non-operating income		
Interest income	533	1,047
Dividend income	3	5
Foreign exchange gains	35,051	48,518
Other	177	22
Total non-operating income	35,765	49,593
Non-operating expenses		
Interest expenses	1,781	2,185
Amortization of restricted stock remuneration	435	2,183
Share acquisition rights issuance costs	–	2,310
Share issuance costs	–	2,466
Other	–	73
Total non-operating expenses	2,217	9,219
Ordinary loss	(867,441)	(752,997)
Extraordinary income		
Gain on sale of non-current assets	136	–
Total extraordinary income	136	–
Loss before income taxes	(867,305)	(752,997)
Income taxes - current	1,457	1,871
Total income taxes	1,457	1,871
Loss	(868,762)	(754,868)

(3) Semi-annual Statements of Cash Flows

(Thousand yen)

	For the six months ended June 30, 2023	For the six months ended June 30, 2024
Cash flows from operating activities		
Loss before income taxes	(867,305)	(752,997)
Depreciation	141	–
Amortization of restricted stock remuneration	435	2,183
Share-based remuneration expenses	5,488	6,862
Increase (decrease) in provision for retirement benefits	(153)	(1,109)
Interest and dividend income	(536)	(1,052)
Interest expenses	1,781	2,185
Share acquisition rights issuance costs	–	2,310
Share issuance costs	–	2,466
Foreign exchange losses (gains)	(34,696)	(29,522)
Decrease (increase) in notes and accounts receivable – trade	–	(32,206)
Decrease (increase) in inventories	15,297	1,064
Decrease (increase) in prepaid expenses	(1,083)	(8,607)
Decrease (increase) in accounts receivable – other	149,396	(82,953)
Decrease (increase) in consumption taxes refund receivable	54,519	27,981
Decrease (increase) in advance payments – other	192,523	(107,125)
Increase (decrease) in accounts payable – other	31,576	(147,462)
Other, net	5,761	(1,406)
Subtotal	(446,855)	(1,119,389)
Interest and dividend income received	243	25
Interest expenses paid	(2,017)	(1,862)
Income taxes paid	(2,923)	(2,927)
Net cash provided by (used in) operating activities	(451,552)	(1,124,153)
Cash flows from investing activities		
Purchase of property, plant and equipment	(951)	–
Proceeds from sale of property, plant and equipment	136	–
Payments of leasehold and guarantee deposits	–	(1,424)
Proceeds from refund of lease and guarantee deposits	66	240
Net cash provided by (used in) investing activities	(748)	(1,184)
Cash flows from financing activities		
Proceeds from long-term loans payable	100,000	100,000
Repayments of long-term loans payable	(52,774)	(44,440)
Repayments of lease obligations	(1,780)	(4,929)
Proceeds from issuance of common shares	–	638,294
Payments for issuance of shares	–	(2,466)
Net cash provided by (used in) financing activities	45,445	686,458
Effect of exchange rate change on cash and cash equivalents	30,994	23,573
Net increase (decrease) in cash and cash equivalents	(375,860)	(415,305)
Cash and cash equivalents at beginning of period	1,466,201	1,287,763
Cash and cash equivalents at end of period	* 1,090,340	* 872,457

(4) Notes to Semi-annual Financial Statements

(Notes on going concern assumption)

There is no relevant information.

(Notes in the case of significant changes in shareholders' equity)

The Company received payments for the exercise of share acquisition rights during the semi-annual period of the fiscal year under review. Furthermore, the Company issued new shares as restricted stock remuneration on April 2, 2024, based on the resolution by the Board of Directors at its meeting held on March 15, 2024. As a result, capital stock increased by ¥352,436 thousand and legal capital surplus increased by ¥352,340 thousand during the six months ended June 30, 2024. At the end of the period, capital stock was ¥3,975,601 thousand and legal capital surplus was ¥1,561,930 thousand.

(Segment information, etc.)

[Segment information]

I. 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.

II. For the six months ended June 30, 2024

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, 2023	For the six months ended June 30, 2024
Goods / Services transferred at a point in time	63,038	31,384
Goods / Services transferred over time	–	–
Revenue from contracts with customers	63,038	31,384
Revenue from other sources	–	–
Net sales to outside customers	63,038	31,384

(Significant subsequent events)

1. Issuance of 20th series share acquisition rights (with exercise price adjustment clause and exercise suspension clause) through third-party allotment

The Company resolved, at the Board of Directors meeting held on June 14, 2024, to issue share acquisition rights (with exercise price adjustment clause and exercise suspension clause) (hereinafter, the "Share Acquisition Rights") through third-party allotment by designating EVO FUND as a scheduled allottee, and confirmed the completion of the payment of the total issue price on July 1, 2024.

Outline of the 20th series share acquisition rights (with exercise price adjustment clause and exercise suspension clause) through third-party allotment

Date of allotment	July 1, 2024
Number of share acquisition rights issued	40,000 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	55 yen per Share Acquisition Right (Total amount: 2,200,000 yen)

<table>
<tr><td>Number of potential shares resulting from the issuance</td><td>Number of potential shares: 4,000,000 shares
There is no upper limit of exercise price.
While the lower limit of exercise price is 349 yen, the number of potential shares even at the lower limit of exercise price is 4,000,000 shares.</td></tr>
<tr><td>Amount of funds to be procured</td><td>2,786,200,000 yen (estimated net proceeds) (Note)</td></tr>
<tr><td>Exercise price and conditions for adjustment of exercise price</td><td>Initial exercise price: 698 yen
The exercise price is adjusted, on the effective date of each exercise request of the Share Acquisition Rights, to the amount equivalent to 100% 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.</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>EVO FUND</td></tr>
<tr><td>Exercisable period</td><td>From July 2, 2024 to March 3, 2025</td></tr>
<tr><td>Use of funds</td><td><table>
<tr><th>Specific use</th><th>Amount (million yen)</th></tr>
<tr><td>(i) Costs for manufacture, sale and distribution of Telomelysin</td><td>1,066</td></tr>
<tr><td>(ii) Working capital mainly for establishing manufacturing and sales system for Telomelysin and its maintenance</td><td>1,512</td></tr>
<tr><td>(iii) Costs for joint development system of Telomelysin with MSD</td><td>208</td></tr>
<tr><td>Total</td><td>2,786</td></tr>
</table></td></tr>
<tr><td>Other</td><td>The Company executed an agreement on purchase of the Share Acquisition Rights with the scheduled allottee to mainly stipulate an exercise commitment clause, exercise suspension clause, and that approval by resolution of the Board of Directors of the Company is required in the case where the scheduled allottee transfers the Share Acquisition Rights.</td></tr>
</table>

(Note) The amount of funds to be procured is the sum of the 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. If the exercise price is revised or adjusted, the amount of funds procured may increase or decrease. Furthermore, the amount of funds procured will decrease if the Share Acquisition Rights are not exercised within their exercisable period and if the Company cancels the Share Acquisition Rights it acquired. The amount of property to be contributed upon exercise of the Share Acquisition Rights used for the calculation of the above-mentioned amount of the funds to be procured is the amount assuming that all the Share Acquisition Rights are exercised with the initial exercise price, and therefore the actual procurement amount may change depending on the market environment at the time of exercising the Shared Acquisition Rights.

2. Capital increase through exercise of share acquisition rights

During the period starting on July 1, 2024 and ending on July 31, 2024, a portion of the 20th series Share Acquisition Rights was exercised as follows:

(1) Class and number of shares issued	819,000 shares of common stock
(2) Number of units of share acquisition rights exercised	8,190 units
(3) Total amount exercised	469,079 thousand yen
(4) Amount of increase in capital stock	234,764 thousand yen
(5) Amount of increase in legal capital surplus	234,764 thousand yen

(Notes) 1. (4) Amount of increase in capital stock and (5) Amount of increase in legal capital surplus include transfer of share acquisition rights of 225 thousand yen each.

2. As a result of the above issuance of new shares upon exercise of stock acquisition rights, the total number of shares issued and outstanding as of July 31, 2024 was 21,780,600 shares, capital stock was 4,210,366 thousand yen, and legal capital surplus was 1,796,695 thousand yen.

3. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the six months ended June 30, 2024 totaled ¥523,975 thousand for the drug discovery business. The status of research and development activities during the six months ended June 30, 2024 is as follows.

(1) Research and development structure

As of June 30, 2024, 19 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 completed 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, and is in consultations with PMDA for submitting a new drug application in Japan. In February 2024, we signed an agreement with FUJIFILM Toyama Chemical Co., Ltd. (hereinafter "FUJIFILM Toyama Chemical") to collaborate with Telomelysin sales and established a supply chain for Telomelysin from Henogen SA (in the Thermo Fisher Group, Belgium), the manufacturer, to medical institutions providing treatments, as well as are promoting various consultations regarding a sales system after products are launched in the market. Furthermore, preparations are also underway to obtain approval for manufacture and sale of regenerative medical products. Accordingly, the Company moves from the conventional single business model dependent on licenses to a "hybrid business model" that combines a pharmaceutical company-type business model and a license-type business model.

Meanwhile, in the U.S., in December 2023, the Company signed an agreement with Cornell University, which in turn signed an agreement with Merch Sharp & Dohme LLC. (hereinafter "MSD"), to establish a joint development system for Telomelysin and the pembrolizumab. Based on this system, the Company and MSD equally share research and development expenses for a Phase II investigator-initiated clinical trial for the treatment of gastric cancer.

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 (101JP trial);
ii) Phase II investigator-initiated clinical trial of second-line treatment in combination with immune checkpoint inhibitors for gastric cancer/gastroesophageal junction cancer; and
iii) Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer

i) **Phase II clinical trial in combination with radiation therapy for esophageal cancer (101JP trial)**

This clinical trial was conducted based on the "SAKIGAKE designation" of April 2019 at 17 clinical trial sites around Japan. The results of the clinical trial were deemed as follows, in consultations with medical experts and biological statisticians. Based on these results, the Company is currently in consultations with PMDA regarding non-clinical trials, clinical trials, manufacturing, etc., to submit a new drug application of Telomelysin in Japan.

i-a) **Research and development activities**

Efficacy

The primary endpoint of "local complete response rate" (L-CR rate) was 41.7% (round off to the first decimal place; the same shall apply hereinafter), as evaluated by the Endoscope Central Judgment Committee. It was confirmed that the result was higher than the efficacy threshold of 30.2%, which was indicated in the protocol beforehand. In addition, the secondary endpoint of "local remarkable response rate" (L-RR rate; the cases in which the primary lesion did not completely disappear but shrink remarkably) was 16.7% and "local response rate" including L-CR ([L-CR + L-RR] rate) was 58.3%.

Furthermore, the one-year survival rate at the time of data cut-off in this study was 71.4%, which exceeded the one-year survival rate in the radiotherapy alone of 57.4% in "The Japan Esophageal Society national registered data."

At the time of 18 months, which is the longest follow-up period of this study, the local response rate was 63.9% and the local complete response rate was 50.0%. In addition, although the total survival rate at the time of 18 months was 53%, the cancer survival rate was 70% and the cancer survival rate of patients with local response was 90%.

Moreover, improvement was recognized in 71% of patients with symptoms of dysphagia, which is included in the assessment of QoL (Quality of Life) for esophageal cancer patients. These results suggested a possible increase in patient survival rates from the effect of Telomelysin on esophageal cancer locations.

Safety

The main side-effects related to Telomelysin included fever of 51.4% and the reduction of lymphocyte count or lymphopenia of 48.6%, both of which were mild to moderate or temporary change.

i-b) **Business activities**

The significant supply chain for stable supply of Telomelysin is divided into the preceding process of "through manufacturer, import, and shipment" and the post-process of "from FUJIFILM Toyama Chemical to medical institutions." For Telomelysin sales, the Company needs to obtain approval for manufacture and sale of regenerative medical products, in addition to approval for a new drug.

Supply chain through manufacturer, import, and shipment

The Company is conducting commercial production and validation quality tests at Henogen SA, with a view to submitting a new drug application for Telomelysin. Regarding "turbidness" of the solution observed in the final drug formulation of Telomelysin, its analysis and verification of the cause are underway, and a drug formulation with a new prescription that does not generate "turbidness" has also been confirmed. Furthermore, our Kobe Research Lab is promoting a GCTP system for conducting quality tests for Telomelysin after import, while Eurofins Analytical Science Laboratories (Kyoto City), a party entrusted with the quality tests, is preparing for establishment of a determination system for shipment of Telomelysin. Telomelysin, which has been determined to be ready for shipment, is shipped to FUJIFILM Toyama Chemical, our distribution partnership.

Supply chain from FUJIFILM Toyama Chemical to medical institutions

The Company concluded a sales collaboration agreement with FUJIFILM Toyama Chemical in February 2024 to efficiently deliver Telomelysin, which has been determined to be ready for final shipment, to medical facilities in Japan. After a determination for shipment, Telomelysin is shipped from the Company to FUJIFILM Toyama Chemical, and provided to medical facilities through medical products companies designated by FUJIFILM Toyama Chemical. Currently, the Company has various consultations, such as "establishing the details of a series of supply chains" and "collecting safety information, including side-effects, that must be implemented after medical products are launched in the market and establishing a reporting system to the Ministry of Health, Labour and Welfare," with FUJIFILM Toyama Chemical for smooth supply of Telomelysin after products are launched in the market.

Manufacture and sale of regenerative medical products

The Company will be positioned as a manufacturer and distributor shipping Telomelysin to Japan. Accordingly, before applying for approval of Telomelysin, its manufacturing and marketing are subject to review by the Tokyo Metropolitan Government for conformity to "GQP (Good Quality Practice)," and "GVP (Good Vigilance Practice)" and other requirements, and the Company needs to obtain approval for manufacture and sale of regenerative medical products.

In January 2024, the Company completed the designation for the three roles of marketing director, quality assurance manager, and safety management manager for manufacturing and marketing, and also established the Reliability Assurance Division. Looking forward, we will further strengthen a system that conforms with GQP and GVP.

ii) **Phase II investigator-initiated clinical trial of second-line treatment in combination with immune checkpoint inhibitors for gastric cancer/gastroesophageal junction cancer**

Regarding the above ii) "Phase II investigator-initiated clinical trial of second-line treatment in combination with immune checkpoint inhibitors for gastric cancer/gastroesophageal junction cancer," Cornell University in the U.S. proposed the implementation of a new clinical trial and the payment of clinical trial expenses to MSD, after obtaining the prior agreement of the Company. In December 2023, agreements were concluded between the Company and Cornell University and between Cornell University and MSD, which established a joint development system.

This clinical trial combines the use of Telomelysin and pembrolizumab as second-line treatment for patients with gastric/gastroesophageal junction cancer that is resilient to first-line treatment including anti- PD-1/PD-Li antibodies. Currently, the expenses for the clinical trial are shared equally between the Company and MSD, and administration is underway.

If this second-line treatment for gastric cancer combining Telomelysin becomes established, it may provide a greater opportunity for major pharmaceutical companies that sell anti- PD-1/PD-Li antibodies to prescribe immune checkpoint inhibitors. The Company expects that the results of this clinical trial will lead to licensing activities for

Telomelysin overseas.

iii) **Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer**

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 being conducted in six facilities within the U.S., and the enrollment of the second stage is underway. 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 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 LINE-1 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 IIb clinical trials as a treatment drug for HIV infection. The results demonstrated the non-inferiority of OBP-601 to existing drugs. 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, resulting in withdrawal from the HIV field, the license agreement was terminated. Results of a study by Brown University of the U.S. then suggested that nucleic acid-based reverse transcriptase inhibitors (NRTIs) of HIV suppress the aberrant expression of a retrotransposons. Subsequent research confirmed that OBP-601, which has the same effect, has high brain translocability compared to other NRTIs and strongly suppresses the production of a retrotransposon by greatly inhibiting a reverse transcriptase called LINE-1.

In June 2020, we concluded a licensing agreement worth more than $300 million worldwide with Transposon which had been planning to apply OBP-601 to the treatment of intractable neurological diseases focusing on this mechanism. In November of the same year, Transposon achieved its first milestone.

Currently, Transposon, a licensee, concluded enrollment of two double-blind Phase IIa clinical trials that make use of placebos. 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, enrollment is proceeding under a single-arm Phase IIa clinical trial in Europe for the treatment of Aicardi-Goutières Syndrome (AGS).

These clinical trials on OBP-601 are proceeding entirely at Transposon's expense based on the license agreement. In addition, Transposon is carrying out business activities based on the license agreement and may grant sublicenses for OBP-601 to pharmaceutical companies and other third parties. If Transposon achieves business results, including sublicense agreements for OBP-601 with third parties, it will pass on a certain percentage of revenue it obtains from the sublicensees to the Company.

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 and expects Transposon to achieve business results.

i) **Phase IIa clinical trial for PSP**

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. Transposon disclosed the main details of the trial as follows at the 18th Alzheimer's and Parkinson's Diseases Conference (AD/PD2024) in March 2024.

1) The clinical trials incorporated 42 PSP patients with an average age of 69 years and an average illness duration of 3.8 years.
2) In these double-blind trials, administration was conducted for 6 months, then administration was switched to 400 mg of OBP-601 for all patients and follow-up was provided for 6 months.
3) OBP-601 indicated tolerability for PSP patients, with a serious side effect of loss of consciousness (1 patient in the 100 mg group).
4) Regarding the reduction of neurofilament light chains (hereinafter "NfL") in cerebrospinal fluid, continued reduction in the 400 mg administration group was indicated, but in the placebo group an increase over 24 weeks and then a reduction after switching to 400 mg administration in the follow-up period were indicated.
5) IL-6 indicated a similar change in cerebrospinal fluid.
6) OBP-601 slowed the worsening of symptoms measured on the Progressive Supranuclear Palsy Rating Scale (PSPRS).
7) The clinical trials suggested that OBP-601 suppresses neurological damage from neuroinflammation and the progression of illness by suppressing Line-1 in the brain.

Transposon is currently moving forward on specific preparations for Phase III clinical trials for PSP with the U.S.

Food & Drug Administration (FDA), such as holding the End of Phase II meeting to aim for starting Phase III clinical trials for PSP in parallel with business activities.

ii) **Phase IIa clinical trial for C9-ALS/FTD**

Administration under the clinical trial for C9-ALS/FTD began in January 2022, and target enrollment was concluded in March 2023. We have also completed 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. The main final analysis results of the trial related to ALS after 48 weeks are as follows:

1) The OBP-601 administration group decreased the deterioration rate of Vital Capacity, which is an objective indicator of respiratory function that correlates with C9-ALS patient mortality, by approximately 50% compared with the placebo administration group in the 24 weeks from the start of administration.
2) The assessment using a scale for assessment of ALS function (ALSFRS-R) indicated effects of suppressing the progression of illness.
3) The OBP-601 administration group reduced primary biomarkers of neurodegeneration and neuroinflammation including NfL, neurofilament heavy chains (hereinafter "NfH"), and IL-6.
4) The OBP-601 administration group indicated a decrease in significant values of NfL in a meta-analysis that comprehensively analyzed Phase II clinical trials for C9-ALS/FTD and PSP.
5) Transposon plans to move forward with Phase III clinical trials on OBP-601 for C9-ALS.

iii) **Phase IIa clinical trial for AGS**

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, in Europe. To date, there have been no reports of safety problems that necessitate the termination of the trials.

3) 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 uses a novel oncolytic virus that carries the powerful in vivo 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 concentrate management resources on Telomelysin to submit for approval.

4) Activities related to OBP-2011 for the treatment of viral infectious diseases

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 to apply for approval. Going forward, the Company will proceed with clarifying the detailed mechanism of action for OBP-2011 by conducting collaborative research with Kagoshima University and will consider new indications for RNA viruses other than coronaviruses, maintaining a framework that can respond to new pandemics.

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

The Company is conducting image learning of cancer cells that TelomeScan fluoresced for automatic judgment by AI, aimed at establishing a platform for automated detection. However, the development has been delayed due to more time required to acquire the large number of images for image learning than initially planned. We have lowered the priority of these activities in order to concentrate management resources on Telomelysin to submit for approval.

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). Furthermore, use invention of OBP-801 related to “suppression of filtering bleb fibrosis after glaucoma surgery” and “age-related macular degeneration” received patents in Japan in July 2024. We have lowered the priority of these activities in order to concentrate management resources on Telomelysin to submit for approval.

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 (NDA preparation)
		Chemoradiotherapy	U.S.	Phase I
		Anti-PD-1 antibody pembrolizumab	Japan	Phase I (complete)
	Gastric/ gastroesophageal junction cancer	Anti-PD-1 antibody pembrolizumab	U.S.	Phase II (complete)
		Immune checkpoint inhibitor pembrolizumab	U.S.	Phase II
	Hepatocellular cancer (HCC)	Monotherapy	South Korea and Taiwan	Phase I (complete)
OBP-601 (censavudine)	Progressive supranuclear palsy (PSP)	Monotherapy	U.S.	Phase IIa (Phase III preparation)
	Amyotrophic lateral sclerosis (C9-ALS) / frontotemporal degeneration (FTD)	Monotherapy	U.S. and Europe	Phase IIa (Phase III preparation)
	Aicardi-Goutières Syndrome (AGS)	Monotherapy	Europe	Phase IIa
OBP-702	Solid tumor	Anti-PD-(L)1 antibody (expected)	Japan	Pre-clinical
OBP-2011	Viral infectious diseases	TBD	Japan	Pre-clinical
TelomeScan (OBP-401)	Solid tumor	—	Japan	Clinical research
OBP-801	Suppression of filtering bleb fibrosis after glaucoma surgery	—	Japan	Pre-clinical