# Non-consolidated Financial Results for the Nine Months Ended September 30, 2021 [Japanese GAAP]

November 5, 2021

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: November 5, 2021
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, 2021 (January 1, 2021 to September 30, 2021)

(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, 2021 | 318 | 53.3 | (963) | - | (976) | - | (979) | - |
| September 30, 2020 | 207 | (67.5) | (1,167) | - | (1,185) | - | (1,545) | - |

| | Basic earnings per share | Diluted earnings per share |
|---|---|---|
| Nine months ended | Yen | Yen |
| September 30, 2021 | (58.42) | - |
| September 30, 2020 | (107.64) | - |

(2) Financial Position

| | Total assets | Net assets | Equity ratio |
|---|---|---|---|
| | Million yen | Million yen | % |
| As of September 30, 2021 | 4,883 | 4,152 | 84.9 |
| As of December 31, 2020 | 2,796 | 2,003 | 71.4 |

(Reference) Equity: As of September 30, 2021: ¥4,144 million
As of December 31, 2020: ¥1,995 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, 2020 | - | 0.00 | - | 0.00 | 0.00 |
| Fiscal year ending December 31, 2021 | - | 0.00 | - | | |
| Fiscal year ending December 31, 2021 (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, 2021 (January 1, 2021 to December 31, 2021)**

(% indicates changes from the previous corresponding period.)

| | Net sales | | Operating profit | | Ordinary profit | | Profit | | Basic earnings per share |
|---|---|---|---|---|---|---|---|---|---|
| | Million yen | % | Million yen | % | Million yen | % | Million yen | % | Yen |
| Full year | 350 ~ 700 | 111.4 ~ 222.9 | (2,000) ~ (1,650) | - | (2,000) ~ (1,650) | - | (2,000) ~ (1,650) | - | (136.59) ~ (112.69) |

(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: No
2) Changes in accounting policies other than 1) above: No
3) Changes in accounting estimates: No
4) Retrospective restatement: No

(3) Total number of issued shares (common shares)
1) Total number of issued shares at the end of the period (including treasury shares):
September 30, 2021: 17,341,100 shares
December 31, 2020: 14,641,900 shares

2) Total number of treasury shares at the end of the period:
September 30, 2021: 36,462 shares
December 31, 2020: 14,462 shares

3) Average number of shares during the period:
Nine months ended September 30, 2021: 16,770,384 shares
Nine months ended September 30, 2020: 14,356,563 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 4 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

Uncertainty about the future continued to prevail in the Japanese economy during the nine months ended September 30, 2021, as a state of emergency and priority preventative measures were issued in multiple prefectures in response to the renewed spread of COVID-19 led especially by the delta variant, first detected in India. On the other hand, the number of newly infected people trended downward and there were signs of recovery in production activity, as a result of the government measures taken to prevent infection and the promotion of vaccination, followed by additional measures and the economic recovery abroad.

Under these circumstances, Oncolys BioPharma Inc. (hereinafter "the Company") endeavored to increase management efficiency and actively expanded its research, development, and licensing activities in the drug discovery business. For details of the Company's activities, please refer to "3. Supplemental Information (1) Research and development activities."

The Company was previously composed of two reportable segments classified as the "pharmaceutical business" and the "diagnostic business." However, since more than 99% of net sales of the Company are from the pharmaceutical business and the trend is expected to continue, the Company changed the method of performance management and changed to a single segment of the "drug discovery business" from the first quarter of the fiscal year under review. Information by segment is therefore omitted.

In the drug discovery business during the nine months ended September 30, 2021, Chugai Pharmaceutical Co., Ltd. (hereinafter "Chugai"), with which the Company entered into a licensing agreement for the development of the Telomelysin virotherapy in April 2019 (hereinafter the "Agreement"), pushed ahead with the clinical trial in Japan of the treatment used in combination with radiation therapy for esophageal cancer as well as a clinical trial for hepatocellular cancer. However, Chugai, which was working on the solicitation of patients to participate in the "Phase I clinical trial in combination with chemoradiotherapy for esophageal cancer" and planning on "Phase I clinical trial in combination with atezolizumab, an anti-PD-L1 antibody, and chemoradiotherapy for head and neck cancer," decided to cancel both trials due to factors including delays in the manufacturing of Telomelysin investigational drugs, which the Company was responsible for and outsourced, and impact of case registration because of the number of has been increasing of COVID-19 patients.

Furthermore, as explained in "Announcement of Cancellation of Telomelysin Licensing Agreement" released on October 19, 2021, the Company and Chugai decided that "continuation of the development under the tie-up deal between the two companies may not lead to maximizing Telomelysin's product value" and, after considering the Company's future business strategy from a comprehensive perspective, agreed to cancel the Agreement. Also, both Chugai and the company emphasize that this decision was in no way related to the efficacy or the safety of Telomelysin.

The official date of cancellation of the Agreement, which will remain effective until October 2022 at the latest, will be decided after negotiations with Chugai. Therefore, the clinical trial being conducted by Chugai in Japan will be proceeded by Chugai, which is responsible for clinical trials, as long as the Agreement remains effective. The Company will continue to negotiate with Chugai to decide the share of manufacture and development costs for Telomelysin to be taken on by each company.

The Company decided to contract out the production of Telomelysin to Belgium's Henogen SA, which has a wealth of experience in manufacturing virus vectors, as the second contractor after Lonza Houston, Inc. of the United States, our existing contractor. This is aimed at enhancing the manufacturing framework for Telomelysin toward its commercialization and diversifying manufacturing locations to mitigate risks.

The Company now plans to work on its own to apply for approval for Telomelysin in Japan. Under this assumption, the Company will work to prepare pharmaceutical affairs and clinical development structures toward achieving the application for approval in 2024. The Company, however, intends to seek partners for Telomelysin's

sales and distribution after its launch. As regards regions outside Japan, the Company will proceed with the clinical trial of Telomelysin under way in the United States while at the same time pursuing new opportunities for licensing agreements.

As regards OBP-2011 for the treatment of COVID-19, the Company confirmed its effectiveness against coronavirus variants identified in India and South Africa, respectively through in vitro experiments. As a result, its effectiveness was confirmed on all "Variants of Concern (VOC)" designated by the World Health Organization, namely: alpha (first detected in the United Kingdom), gamma (first detected in Brazil), delta (first detected in India), and beta (first detected in South Africa). In addition to these results, OBP-2011 exhibited a similar degree of effectiveness against viruses that cause the severe acute respiratory syndrome (SARS) and the Middle East respiratory syndrome (MERS), proving its effectiveness in suppressing the growth of a wide variety of coronaviruses. Furthermore, pharmacokinetic study results in rats and dogs demonstrated its oral absorbability.

The Company commissioned GMP manufacturing of formulations for investigational drugs to SPERA PHARMA, Inc. The Company is working on the development with Shin Nippon Biomedical Laboratories, Ltd. (hereinafter "SNBL"), with which the Company has concluded a joint research agreement on preclinical development, and Spera Nexus, Inc. (previously known as Iwaki Seiyaku Co., Ltd.), to whom the Company commissions GMP manufacturing of active pharmaceutical ingredients for investigational drugs, with an eye on applying for clinical trials by the end of the first half of 2022.

As a result, for the nine months ended September 30, 2021, net sales were ¥318,317 thousand (net sales of ¥207,611 thousand in the same period of the previous year), and operating loss was ¥963,649 thousand (operating loss of ¥1,167,504 in the same period of the previous year). In addition, the Company recorded interest income of ¥382 thousand, foreign exchange gains of ¥28,541 thousand, and other items as non-operating income, and interest expenses of ¥3,191 thousand, amortization of restricted stock remuneration of ¥28,116 thousand, share issuance costs of ¥11,007 thousand, and other items as non-operating expenses. As a result, ordinary loss was ¥976,891 thousand (ordinary loss of ¥1,185,938 thousand in the same period of the previous year), and loss was ¥979,679 thousand (loss of ¥1,545,408 thousand in the same period of the previous year).

(2) Explanation of Financial Position

Assets at the end of the third quarter of the fiscal year under review were ¥4,883,402 thousand (74.6% increase compared with the end of the previous fiscal year), owing partly to a ¥1,871,998 thousand increase in cash and deposits due to capital increase through issuance of new shares, a ¥411,576 thousand increase in advance payments – other. Liabilities were ¥731,174 thousand (7.8% decline compared with the end of the previous fiscal year), owing partly to a decline in accounts payable – other. Net assets were ¥4,152,227 thousand (107.3% increase compared with the end of the previous fiscal year), owing to capital increase through issuance of new shares, loss incurred and other factors.

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

For the fiscal year ending December 31, 2021, the Company forecasts net sales of ¥350 million to ¥700 million, operating loss, ordinary loss, and net loss of ¥1,650 million to ¥2,000 million.

These forecasts are based on assumed rates of ¥110 per U.S. dollar and ¥134 per euro.

The Company has signed new licensing agreements, including a license agreement for Telomelysin with Chugai in April 2019 and an OBP-601 license agreement with Transposon Therapeutics, Inc. (hereinafter "Transposon") in June 2020. The Company will continue to actively promote business activities aimed at concluding new contracts with major pharmaceutical companies, with a focus on the licensing activities of Telomelysin to the Chinese region and strive to increase corporate value.

In R&D activities, the Company will actively promote clinical trials of various pipelines, nonclinical studies, investigational drug manufacturing, and manufacturing method development for launch, in Japan and overseas, focusing on Telomelysin, OBP-2011 for the treatment of COVID-19, and OBP-702.

The plan is to allocate funds raised through the "Notice concerning the issuance of new shares and the 18th Stock Acquisition Rights (with exercise price amendments) through third party allotment and the conclusion of facility agreements (with suspension of exercise designation clauses)" announced on December 10, 2020 and business income.

However, due to the worldwide spread of COVID-19 infections, the proper and reasonable prospects for business and R&D activities are unclear. Therefore, the Company considered it appropriate to publish a range-style earnings forecast.

## 2. Quarterly Financial Statements and Primary Notes

### (1) Quarterly Balance Sheets

(Thousand yen)

| | As of December 31, 2020 | As of September 30, 2021 |
|---|---|---|
| Assets | | |
| Current assets | | |
| Cash and deposits | 2,067,927 | 3,939,926 |
| Accounts receivable – trade | 70,598 | 127,212 |
| Finished goods | 8,434 | 8,434 |
| Supplies | 2,038 | 1,591 |
| Advance payments – other | 43,354 | 454,931 |
| Prepaid expenses | 241,379 | 139,688 |
| Accounts receivable – other | 1,544 | 129 |
| Consumption taxes receivable | 95,445 | 20,307 |
| Advances paid | 14,935 | 2,132 |
| Other | 16 | 13 |
| Total current assets | 2,545,676 | 4,694,369 |
| Non-current assets | | |
| Property, plant and equipment | | |
| Buildings | 2,794 | 2,794 |
| Accumulated depreciation | (2,794) | (2,794) |
| Buildings, net | — | — |
| Tools, furniture and fixtures | 87,525 | 85,712 |
| Accumulated depreciation | (66,207) | (64,904) |
| Tools, furniture and fixtures, net | 21,317 | 20,808 |
| Total property, plant and equipment | 21,317 | 20,808 |
| Intangible assets | | |
| Software | 650 | 500 |
| Total intangible assets | 650 | 500 |
| Investments and other assets | | |
| Investment securities | 458 | — |
| Shares of subsidiaries and associates | 111,916 | 111,916 |
| Investments in capital | 100 | 100 |
| Long-term loans receivable from subsidiaries and associates | 31,050 | 33,585 |
| Lease and guarantee deposits | 21,229 | 21,220 |
| Long-term prepaid expenses | 63,996 | 884 |
| Other | 19 | 19 |
| Total investments and other assets | 228,769 | 167,725 |
| Total non-current assets | 250,736 | 189,033 |
| Total assets | 2,796,413 | 4,883,402 |

(Thousand yen)

| | As of December 31, 2020 | As of September 30, 2021 |
|---|---|---|
| Liabilities | | |
| Current liabilities | | |
| Short-term loans payable | 150,008 | 149,992 |
| Lease obligations | 2,144 | 2,659 |
| Accounts payable – other | 206,610 | 56,658 |
| Accrued expenses | 15,333 | 18,096 |
| Income taxes payable | 33,486 | 34,424 |
| Deposits received | 7,661 | 90,075 |
| Total current liabilities | 415,244 | 351,906 |
| Non-current liabilities | | |
| Long-term loans payable | 366,648 | 366,656 |
| Lease obligations | 6,275 | 7,047 |
| Provision for retirement benefits | 4,920 | 5,565 |
| Total non-current liabilities | 377,843 | 379,268 |
| Total liabilities | 793,087 | 731,174 |
| Net assets | | |
| Shareholders' equity | | |
| Capital stock | 7,436,537 | 9,000,735 |
| Capital surplus | | |
| Legal capital surplus | 7,428,925 | 8,993,123 |
| Other capital surplus | 31,740 | 31,740 |
| Total capital surpluses | 7,460,666 | 9,024,864 |
| Retained earnings | | |
| Other retained earnings | | |
| Retained earnings brought forward | (12,901,296) | (13,880,976) |
| Total retained earnings | (12,901,296) | (13,880,976) |
| Treasury shares | (76) | (76) |
| Total shareholders' equity | 1,995,830 | 4,144,547 |
| Valuation and translation adjustments | | |
| Valuation difference on available-for-sale securities | (254) | — |
| Total valuation and translation adjustments | (254) | — |
| Share acquisition rights | 7,750 | 7,680 |
| Total net assets | 2,003,325 | 4,152,227 |
| Total liabilities and net assets | 2,796,413 | 4,883,402 |

(2) Quarterly Statements of Income

Nine Months Ended September 30

(Thousand yen)

| | For the nine months ended September 30, 2020 | For the nine months ended September 30, 2021 |
|---|---|---|
| Net sales | 207,611 | 318,317 |
| Cost of sales | 74,309 | 148,936 |
| Gross profit | 133,302 | 169,380 |
| Selling, general and administrative expenses | 1,300,807 | 1,133,029 |
| Operating loss | (1,167,504) | (963,649) |
| Non-operating income | | |
| Interest income | 485 | 382 |
| Foreign exchange gains | — | 28,541 |
| Other | — | 779 |
| Total non-operating income | 485 | 29,703 |
| Non-operating expenses | | |
| Interest expenses | 3,133 | 3,191 |
| Amortization of restricted stock remuneration | 6,342 | 28,116 |
| Share acquisition rights issuance costs | — | 413 |
| Share issuance costs | — | 11,007 |
| Foreign exchange losses | 9,412 | — |
| Other | 30 | 217 |
| Total non-operating expenses | 18,918 | 42,945 |
| Ordinary loss | (1,185,938) | (976,891) |
| Extraordinary losses | | |
| Loss on valuation of investment securities | 321,000 | — |
| Bad debts expenses | 35,681 | — |
| Total extraordinary losses | 356,681 | — |
| Loss before income taxes | (1,542,619) | (976,891) |
| Income taxes - current | 2,789 | 2,787 |
| Total income taxes | 2,789 | 2,787 |
| Loss | (1,545,408) | (979,679) |

(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)

The Company received payments for the exercise of stock acquisition rights during the period from January 5, 2021 to July 16, 2021. As a result, capital stock and legal capital surplus each increased by ¥1,564,198 thousand during the nine months ended September 30, 2021. At the end of the third quarter of the fiscal year under review, capital stock was ¥9,000,735 thousand and legal capital surplus was ¥8,993,123 thousand.

(Segment information, etc.)

[Segment information]

I. For nine months ended September 30, 2020

As described in "For nine months ended September 30, 2021 (Matters related to changes, etc. in reportable segments)."

II. For nine months ended September 30, 2021

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

(Matters related to changes, etc. in reportable segments)

The Company was previously composed of two reportable segments classified as the "pharmaceutical business" and the "diagnostic business." However, since more than 99% of net sales of the Company are from the pharmaceutical business and the trend is expected to continue, the Company changed the method of performance management and changed to a single segment of the "drug discovery business" from the first quarter of the fiscal year under review.

Since the Company now operates as a single segment due to the change explained above, the segment information for the nine months ended September 30, 2020 and for the nine months ended September 30, 2021 is omitted from this report.

(Significant subsequent events)

(Issuance of new shares as restricted stock remuneration)

The Company's Board of Directors resolved to approve a plan to issue new shares as restricted stock remuneration (hereinafter "New Share Issuance") at a meeting on September 17, 2021, with the payment procedure completed on October 4, 2021.

1. Outline of issuance

| | |
|---|---|
| (1) Effective date of payment | October 4, 2021 |
| (2) Class and number of shares issued | Common shares of the Company: 64,100 shares |
| (3) Issuance value | ¥1,210 per share |
| (4) Total value issued | ¥77,561,000 |
| (5) Amount incorporated into capital stock | ¥605 per share |
| (6) Total amount incorporated into capital | ¥38,780,500 |
| (7) Method of offering or allotment | Allotment of specified restricted stock |
| (8) Method of executing investment | Contribution in kind of monetary compensation claims |
| (9) Individuals qualifying for share allotment, their number and number of shares allocated | Directors of the Company*: 4 individuals, 25,000 shares<br>Employees of the Company: 23 individuals, 31,100 shares<br>Employees of the Company's subsidiaries: 4 individuals, 8,000 shares<br>* Excluding Outside Board Members |
| (10) Transfer restriction period | From October 4, 2021 to November 30, 2023 |
| (11) Other | A written notice of securities under the Financial Instruments and Exchange Act was issued regarding the New Share Issuance. |

2. Purpose and reason of issuance

In this fiscal year, the Company and its subsidiaries (hereinafter the "Group") introduced a stock compensation plan (hereinafter the "Plan") under which it allots restricted shares, with a purpose of making our executives and employees share the benefit and risk of share price fluctuations and increasing their motivation to contribute to increasing share prices and improving corporate value more than ever.

At a meeting on September 17, 2021, the Company's Board of Directors resolved to approve a plan to allot 64,100 common shares of the Company as specified restricted stock under a scheme in which the Company pays monetary compensation claims totaling ¥77,561,000 to four Directors (excluding Outside Board Members) and 23 employees of the Company and four employees of the subsidiaries of the Company (hereinafter the "Allottees") and the Allottees provide such monetary compensation claims to the Company in full amount through contribution in kind, as restricted stock compensation for the period from the convocation of the Company's 17th Annual General Meeting of Shareholders to the Company's 18th Annual General Meeting of Shareholders to be held in March 2022 for the Company's Directors (excluding Outside Board Members) targeted for allotment and as restricted stock remuneration for the period from October 4, 2021 to November 30, 2023 for the Company's employees and those of its subsidiaries targeted for allotment.

In order to ensure the purpose of this plan － to make the Allottees share the benefit and risk of share price fluctuation with shareholders and increase their motivation to contribute to increasing share prices and corporate value － will be achieved, the transfer restriction period is set at 2.1 years.

(Cancellation of significant agreement)

As released on October 19, 2021, the Company has agreed with Chugai Pharmaceutical Co., Ltd. (hereinafter "Chugai") to cancel a licensing agreement for the Telomelysin virotherapy (OBP-301: suratadenoturev) (hereinafter the "Agreement") signed with the latter in April 2019.

(1) Reason for cancellation

The Company signed the Agreement with Chugai in April 2019 under which it grants exclusive license for Telomelysin in Japan and Taiwan and option rights in Europe, the United States, and other countries. The Company has so far received a contractual lump-sum payment and the first milestone revenue payment from Chugai.

However, Chugai postponed the target date of application for Telomelysin's approval until 2024 from 2022 after supply of Telomelysin investigational drugs and development of their production method, which the Company was responsible for and outsourced, took longer than expected. Chugai, which initially planned to conduct four clinical trials in Japan, also decided to cancel the "Phase I clinical trial in combination with chemoradiotherapy for esophageal cancer" and "Phase I clinical trial in combination with atezolizumab and chemoradiotherapy for head and neck cancer." At the time of this decision, Chugai was planning to carry on with the development of Telomelysin.

Chugai has now focused Telomelysin-related resources on "Phase II clinical trial in combination with radiation therapy for esophageal cancer" and "Phase I clinical trial in combination with atezolizumab and bevacizumab for hepatocellular cancer," which the company is still conducting.

Recently, the Company and Chugai decided that "continuation of the development under the tie-up deal between the two companies may not lead to maximizing Telomelysin's product value" and, after considering the Company's future business strategy from a comprehensive perspective, agreed to cancel the Agreement. The partners also affirmed that this decision was in no way related to any issues in the efficacy or the safety of Telomelysin.

(2) Name of other party to Agreement

Chugai Pharmaceutical Co., Ltd.

(3) Date of cancellation of Agreement

The Agreement remains effective through October 2022 at the latest. Official date of cancellation will be decided after negotiation with Chugai.

(4) Outline of Agreement

This is a licensing agreement which grants exclusive licensing and sublicensing rights in Japan and Taiwan of Telomelysin's development, manufacture and sale and an exclusive option right concerning the worldwide license for Telomelysin's development, manufacture and sale, excluding Japan, Taiwan, China, Hong Kong and Macau.

(5) Impacts on Company's earnings of cancellation of Agreement

No impact is expected on the financial results for the fiscal year ending December 31, 2021. All rights regarding Telomelysin will be returned to the Company upon cancellation of the Agreement. Milestone payments or revenues under the Agreement will no longer arise between the two companies.

(Significant acquisition of treasury shares)

Following an event associated with the cancellation of the licensing Agreement on Telomelysin on October 19, 2021, the Company received offers to voluntarily return restricted stock remuneration from the full-time Directors and Corporate Officers. As a result, the Company acquired treasury shares at no cost.

1. Class and number of shares acquired: 31,000 common shares of the Company
2. Date of acquisition: October 29, 2021

## 3. Supplemental Information

### (1) Research and development activities

Research and development expenses of the Company in the nine months ended September 30, 2021 totaled ¥491,365 thousand for the drug discovery business. The status of research and development activities for the drug discovery business during the fiscal year under review is as follows.

(1) Research and development structure

As of September 30, 2021, 13 persons belonged to research and development department, equivalent to 37.1% 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 concluded an agreement for exclusive licensing in Japan and Taiwan of Telomelysin virotherapy and exclusive option right concerning the worldwide license for of Telomelysin, excluding Japan, Taiwan, China, Hong Kong, and Macau (hereinafter the "Agreement") with Chugai in April 2019, and the Company has already received a contractual lump-sum payment and the first milestone revenue payment from Chugai under the Agreement.

However, Chugai postponed the target date of application for Telomelysin's approval until 2024 from 2022 after supply of Telomelysin investigational drugs and development of their production method, which the Company was responsible for and outsourced, took longer than expected. Chugai, which initially planned to conduct four clinical trials in Japan, also decided to cancel the "Phase I clinical trial in combination with chemoradiotherapy for esophageal cancer" and "Phase I clinical trial in combination with atezolizumab and chemoradiotherapy for head and neck cancer." At the time of this decision, Chugai was planning to carry on with the development of Telomelysin.

Chugai is currently conducting "Phase II clinical trial in combination with radiation therapy for esophageal cancer" and "Phase I clinical trial in combination with atezolizumab and bevacizumab for hepatocellular cancer."

As announced on October 19, 2021, the Company and Chugai decided that "continuation of the development under the tie-up deal between the two companies may not lead to maximizing Telomelysin's product value" and, after considering the Company's future business strategy from a comprehensive perspective, agreed to cancel the Agreement. The partners also affirmed that this decision was in no way related to any issues in the efficacy or the safety of Telomelysin. The official date of cancellation of the Agreement, which will remain effective until October 2022 at the latest, will be decided after negotiations with Chugai. Therefore, the clinical trial being conducted by Chugai in Japan will be proceeded by the company, which is responsible for clinical trials, as long as the Agreement remains effective. The Company will continue to negotiate with Chugai to decide the share of manufacture and development costs for Telomelysin to be taken on by each company.

Policy for Telomelysin going forward

The Company now plans to work on its own to apply for approval for Telomelysin in Japan. Under this assumption, the Company will work to prepare pharmaceutical affairs and clinical development structures toward achieving the application for approval in 2024. The Company, however, intends to seek partners for Telomelysin's sales and distribution after its launch. As regards regions outside Japan, the Company will proceed with the clinical trial of Telomelysin under way in the United States while at the same time pursuing new opportunities for licensing agreements.

In the U.S., the development of Telomelysin for esophageal cancer was designated as an orphan drug by the U.S. Food and Drug Administration (FDA) in June 2020. This designation entitles the Company to receiving from FDA advice and consultation for the development of Telomelysin, as well as receiving preferential treatment such as subsidies and tax deduction of clinical trial expenses. Furthermore, the drug will be given prior patent protection in the U.S. for seven years after the approval of Telomelysin, which ensures market exclusivity for this period. Along with the "SAKIGAKE Designation System" which designated the drug in April 2019, the Company plans to leverage such systems to develop Telomelysin for the treatment of esophageal cancer.

In February 2021, the World Health Organization (WHO) selected suratadenoturev as the International Nonproprietary Name (INN) for Telomelysin. Selection of the INN by WHO is an important step towards

obtaining approval of a new drug. After the approval, the name will be used across the world.

As of October 22, 2021, the following six clinical trials are under way in Japan and overseas:

i) Phase II clinical trial in combination with radiation therapy for esophageal cancer;
ii) Phase I clinical trial in combination with atezolizumab, an anti-PD-L1 antibody, and bevacizumab, a molecular targeting drug, for hepatocellular cancer;
iii) Phase II investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for gastric cancer/gastroesophageal junction cancer;
iv) Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer;
v) Phase II investigator-initiated clinical trial in combination with radiation therapy and pembrolizumab, an anti-PD-1 antibody, for head and neck cancer; and
vi) Phase I investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for solid tumors.

Regarding the above i) "Phase II clinical trial in combination with radiation therapy for esophageal cancer," administration by Chugai to the first patient began in Japan in March 2020. The targeted number of patients to be administered is 37 for esophageal cancer patients refractory to resection through surgery and definitive chemoradiotherapy.

Although the Company agreed with Chugai to cancel the Agreement, it will remain effective until October 2022 at the latest. The official date of cancellation will be decided through negotiation with Chugai, which will continue to conduct the trials while the Agreement remains effective.

Regarding the above ii) "Phase I clinical trial in combination with atezolizumab, an anti-PD-L1 antibody, and bevacizumab, a molecular targeting drug, for hepatocellular cancer," administration is in progress by Chugai. The trial is the first clinical trial where Telomelysin is administered in combination with atezolizumab, an anti-PD-L1 antibody, and administration to the first patient began in January 2021. The targeted number of patients is 20, and the trial is intended to evaluate primarily safety and secondarily efficacy.

Although the Company agreed with Chugai to cancel the Agreement, it will remain effective until October 2022 at the latest. The official date of cancellation will be decided through negotiation with Chugai, which will continue to conduct the trials while the Agreement remains effective.

Regarding the above iii) "Phase II investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for gastric cancer/gastroesophageal junction cancer," administration to the first patient began in May 2019 led by Cornell University in the U.S. An evaluation of the efficacy and safety of Telomelysin and pembrolizumab, an anti-PD-1 antibody, will be performed for the most advanced stage IV patients. A meeting was held in the U.S. at the end of December 2020 to review interim progress of eight patients, for whom evaluation was possible. Evaluation for one patient indicated partial response (PR) and for another stable disease (SD). Local reaction, which does not happen when pembrolizumab alone is administered, was found for the patient who showed PR. It is highly likely that this is the effect of administering Telomelysin. The Company plans to conduct an interim evaluation of the progress in 18 patients by the end of 2022 and decide whether to continue with the clinical trial.

Regarding the above iv) "Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer," NRG Oncology, a leading cancer research group in the U.S., has been leading the trial. The Company aims to enroll a maximum of 21 patients and begin administration to the first patient. Telomelysin has been designated as an orphan drug in the U.S. as stated above, and this clinical trial will be conducted on that basis.

Regarding the above, v) "Phase II investigator-initiated clinical trial in combination with radiation therapy and pembrolizumab, an anti-PD-1 antibody, for head and neck cancer," administration to the first patient began in May 2021, led by Cornell University in the U.S. In this clinical trial, the systemic clinical effects of Telomelysin used in combination with the anti-PD-1 antibody, in addition to the synergistic local effects of the Telomelysin used in combination with radiation therapy, will be examined. The Company plans to evaluate the progress of 12 patients in 2022 and decide whether to continue with the clinical trial.

Regarding the above vi) "Phase I investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for solid tumors," administration to patients began in December 2017, led by National Cancer

Center Hospital East. As a result of the Phase Ia clinical trial where Telomelysin was administered to the primary tumor of esophagus, the safety of Telomelysin in combination with pembrolizumab, an anti-PD-1 antibody, and efficacy for some of the patients were shown. In the Phase Ib clinical trial currently in progress, 11 patients have been enrolled and followed up. A presentation is scheduled at the upcoming ASCO-GI symposium in January 2022, for which work is underway to compile data at National Cancer Center Hospital East.

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

The Company concluded a joint research agreement with Kagoshima University in 2006, and has promoted drug discovery research with a research group led by Director Masanori Baba of the Joint Research Center for Human Retrovirus Infection at Kagoshima University Campus. As a result, OBP-2001 was identified as a chemical compound fairly effective in suppressing the growth of SARS-CoV-2, which is the virus that causes COVID-19. Furthermore, a comparative experiment in a same experimental system confirmed that the identified compound indicates activity equivalent to or higher than remdesivir (Gilead Sciences, Inc.), an approved treatment for COVID-19. In addition, the findings pointed to mechanisms different from those of remdesivir.

The Company then synthesized new chemical compounds in the joint research with Kagoshima University and identified OBP-2011 among them, which indicated higher activity. Based on the results of pre-clinical trials, it has been confirmed that OBP-2011 can be orally administered. In vitro experiment, it exhibited efficacy against all of the Variants of Concern (VOCs) designated by the World Health Organization: alpha, first detected in the U.K., gamma, first detected in Brazil, delta, first detected in India, and beta, first detected in South Africa. Moreover, the chemical compound was also confirmed to indicate the same level of activity for other coronaviruses, such as those that caused the outbreak of severe acute respiratory syndrome (SARS) in 2002 and Middle East respiratory syndrome (MERS) in 2012, as it does for the wild type, demonstrating effectiveness in suppressing the growth of a broad range of coronaviruses. While many of the orally administered COVID-19 treatments under development by pharmaceutical companies around the world are polymerase or protease inhibitors, experimental outcomes suggest the Company's OBP-2011 is a nucleocapsid inhibitor, which inhibits virus assembly, which occurs in a late stage of the virus growth. It is a new mechanism that differs from those of other treatments under development. It is expected that its effect is not affected by such factors as virus mutation.

The world of the 21st century has already seen three coronavirus pandemics (SARS, MERS, COVID-19), and more pandemics are anticipated in the future. The Company aims to establish POC in the clinical trial targeting early-stage patients and to develop a therapeutic drug that turns patients SARS-CoV-2 negative in a short period of time and can be orally administered, with an eye on applying by the end of 2022 to conduct clinical trials.

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

OBP-702 has two anti-tumor effects which combine the "oncogene therapy" of the powerful cancer suppressor gene p53 with the "oncolytic functions" of Telomelysin (OBP-301). The Company positions OBP- 702 as the "next generation Telomelysin" to follow Telomelysin itself, which has already been licensed to Chugai. In addition, a research group led by Professor Fujiwara of Okayama University conducted non-clinical trials on OBP-702 which was adopted as a grant program of the Japan Agency for Medical Research and Development (AMED) in April 2017 and March 2020, reporting on results of those trials at several conferences. In an experiment on a gemcitabine-resistant pancreatic cancer cell lines using mouse models conducted at Okayama University, OBP-702 used in combination with PD-L1 antibodies exhibited stronger anti-tumor effects than OBP-702 or PD-L1 antibodies administered alone, which has led us to expect to see viable efficacy of the combined use with PD-L1 antibodies in the planned clinical trial.

The Company had originally planned to submit investigational new drug (IND) application for OBP-702 in 2022, but since the validation for GMP manufacturing is taking more time than expected, it now aims for IND submission in the U.S. in 2023.

4) 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 blood. By making use of AI technology, the Company aims to not only reduce the time for processing test results but also improve the sensitivity of CTC image analysis and the accuracy of the tests.

In terms of clinical research, an investigator-initiated clinical research in the field of lung cancer with the Department of Respiratory Medicine, Juntendo University, began in February 2020. Liquid Biotech USA, Inc., with which the Company has a licensing agreement for North America, is conducting joint research activities with research institutions in the U.S. for applications in the fields of lung cancer and female-specific cancer. When the platform under development at Juntendo University is completed, it will be brought into use to drive the diagnostic

business.

5) 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, Bristol-Myers Squibb Co. (hereinafter "BMS") promoted its development up to the completion of Phase II clinical trials as a treatment drug for HIV infection. The license agreement, however, was terminated due to changes in BMS's business strategy. Later on, in June 2020, the Company concluded a new license agreement with Transposon totaling over $300 million. Transposon achieved its first milestone in November 2020.

Transposon is currently conducting two Phase II clinical trials, one on progressive supranuclear palsy (PSP) and the other on amyotrophic lateral sclerosis (ALS) and frontotemporal degeneration (FTD).

Going forward, the Company will continuously monitor the progress of the development of OBP-601 by Transposon, and expect its administration to the first patient in a clinical trial will begin by the end of 2021.

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 was observed in Phase I clinical trials in the U.S., and thus, at present, study enrollment of new patients has been tentatively suspended and the Company is considering the possibility of restarting with another protocol including combinations with other drugs. Furthermore, the Company is exploring its potential use in the ophthalmic field, which is a new area of indication for OBP-801, and the outcome of a study by the Kyoto Prefectural University of Medicine was presented at the World Glaucoma Congress in June 2021.

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 (Chugai)* |
| | | Chemoradiotherapy | U.S. | Phase I |
| | Hepatocellular cancer (HCC) | Anti-PD-L1 antibody atezolizumab Molecular targeting drug | Japan | Phase I (Chugai)* |
| | | - | South Korea and Taiwan | Phase I (complete) |
| | Head and neck cancer | Anti-PD-1 antibody pembrolizumab Radiation therapy | U.S. | Phase II |
| | Gastric/ gastroesophageal junction cancer | Anti-PD-1 antibody pembrolizumab | U.S. | Phase II |
| | Esophageal cancer (solid tumor) | Anti-PD-1 antibody pembrolizumab | Japan | Phase I (complete) |
| OBP-2011 | Novel coronavirus infection (COVID-19) | - | Worldwide | Pre-clinical |
| OBP-702 | Solid tumor | Anti-PD-(L)1 antibody (expected) | U.S./Japan | Pre-clinical |
| OBP-601 (Censavudine) | Amyotrophic lateral sclerosis (ALS) / frontotemporal degeneration (FTD) | - | U.S. | Phase II |
| | Progressive supranuclear palsy (PSP) | - | U.S. | Phase II |
| | HIV infection | - | Europe, the U.S. and others | Phase IIb (complete) |
| OBP-801 | Solid tumor | Anti-PD-(L)1 antibody (expected) | U.S. | Phase I |
| | Ophthalmic field | - | Japan | Pre-clinical |
| TelomeScan (OBP-401) | Solid tumor | - | Japan | Clinical research |

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