Financial Results for the Nine Months ended December 31, 2024
[Japanese GAAP] (non-consolidated)

February 14, 2025

BrightPath Biotherapeutics Co., Ltd. Listed Market Growth, TSE
TSE Code 4594 URL https://www.brightpathbio.com/english/
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Scheduled date of dividend payment commencement : —
Supplementary materials for financial statements : None
Briefing of financial results : None

(Millions of yen, rounded down to the nearest million)

1. Financial results for the nine months ended December 31, 2024 (April 1, 2024 – December 31, 2024)

(1) Results of Operation (Percentages represent changes from the same period of previous year)

	Net sales		Operating income		Ordinary income		Net income	
Nine months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
December 31, 2024	0	33.3	-815	—	-812	—	-815	—
December 31, 2023	0	-98.7	-947	—	-947	—	-953	—

	Net income per share	Fully diluted net income per share
Nine months ended	Yen	Yen
December 31, 2024	-10.30	—
December 31, 2023	-15.14	—

(Note) 1. Fully diluted net income per share is not stated as net loss was recorded for this period although there are residual shares.

(2) Financial Position

	Total assets	Net assets	Equity ratio
As of	Million yen	Million yen	%
December 31, 2024	1,450	1,131	76.5
March 31, 2024	1,230	978	77.7

(Reference) Shareholders' equity As of December 31, 2024 1,110 million yen
As of March 31, 2024 956 million yen

2. Dividends

	Annual dividends per share				
	1Q	2Q	3Q	4Q	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended March 31, 2024	—	0.00	—	0.00	0.00
Fiscal year ending March 31, 2025	—	0.00	—		
Fiscal year ending March 31, 2025 (Forecast)				0.00	0.00

(Note) 1. There is no change in dividends information from the latest official forecast.

3. Projected financial results for the fiscal year ending March 31, 2025 (April 1, 2024 – March 31, 2025)

(Percentages represent changes from the same period of previous year)

	Net sales		Operating income		Ordinary income		Net income		Net income per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
Full year	0	-31.3	-925	—	-925	—	-927	—	-13.08

(Note) 1. The Company manages business results on an annual basis, and therefore only the full-year financial forecasts are disclosed.
2. There is no change in projected financial results from the latest official forecast.

[Notes]

(1) Adoption of accounting treatment specific to the preparation of quarterly non-consolidated financial statements: None

(2) Changes in significant accounting policies, changes in accounting estimates and restatements

1) Changes in accounting policies due to revisions of accounting standards, etc. : None

2) Changes in accounting policies due to other reasons than above 1) : None

3) Changes in accounting estimates : None

4) Restatements : None

(3) Number of shares outstanding (common stock)

1) Number of shares outstanding at the end of the period (including treasury stock)	As of December 31, 2024	87,496,300 shares	As of March 31, 2024	70,741,300 shares
2) Number of shares of treasury stock at the end of the period	As of December 31, 2024	1 share	As of March 31, 2024	1 share
3) Average number of shares during the period	9 months ended December 31, 2024	79,146,408 shares	9 months ended December 31, 2023	63,008,301 shares

* Review of the Japanese-language original of the attached quarterly non-consolidated financial statements by certified public accountants or an audit firm: None
* Explanations regarding appropriate use of forecasts and projections of financial results, and other specific notes
  - All forecasts and projections contained in this document are based on the information available and certain assumptions deemed reasonable by the Company at this time. They are not intended to represent our promise to attain them as a goal. Actual results may differ substantially due to various reasons. For details on the assumptions and conditions for forecasts and projections as well as notes on their use, please refer to “1. Overview of Business Results, etc. (3) Outlook for the Fiscal Year Ending March 31, 2025” on page 4 of the attachment.

Contents of the Attachment

1. Overview of Business Results, etc.

(1) Overview of Operating Results for the Nine Months Ended December 31, 2024

BrightPath Biotherapeutics Co., Ltd. (the "Company") has built an environment for exploring and developing cancer immunotherapeutics (drugs that treat cancer by utilizing the immune system) during the nine months ended December 31, 2024.

Cell therapy agents

<iPSC derived natural killer T-cell (NKT cell) therapy: BP2201>

BP2201 (iPS-NKT) is a candidate agent for novel allogeneic cell therapy. This novel therapy uses natural killer T-cells (NKT cells)[1] manufactured in large quantities through iPS cell technology to treat cancer, since NKT cells have multifaceted anti-tumor effects including cancer-killing capabilities.

The Company has obtained an exclusive license to use the patent for iPSC derived NKT cells (iPS-NKT) from Institute of Physical and Chemical Research, a.k.a. RIKEN. This patent, registered in Japan, the US and the EU, extensively and exclusively protects the use of iPS-NKT for CAR-T cell therapy[2] and other kinds of allogeneic cell therapy. This license has allowed the Company to establish the manufacturing process capable of differentiating iPS cells in the master iPS cell bank into high-purity and high-yield NKT cells and facilitated the Company's introduction of gene-editing technologies. At Chiba University where clinical research for autologous NKT cell therapy has been continued since the beginning of the 2000s, an investigator-initiated Phase 1 trial of iPS-NKT in patients with head and neck cancers started in June 2020 and finished in January 2024. This was the world's first clinical application of iPS-NKT in cellular immunotherapy. This clinical trial demonstrated acceptable tolerability and safety as the primary endpoints and confirmed preliminary anti-tumor activity, as shown by the topline data published at an academic conference in February 2024.

Non-genetically edited iPS-NKT cells used in this clinical trial can serve as a cornerstone or platform for developing novel iPS-NKT cells by transducing CAR-T cells targeting various tumor antigens. Such platform will facilitate the application of iPS-NKT cells to treatment of various types of cancer in many regions of the world.

<CAR-iPSNKT cell therapy: BP2202>

CAR-iPSNKT is a new CAR-T cell therapy using unmodified iPS-NKT cells (BP2201) with chimeric antigen receptors (CAR) that can recognize cancer antigens with the aim of enhancing tumor killing capabilities.

Compared to non-genetically edited iPS-NKT cells, HER2 CAR iPS-NKT experimentally manufactured by the Company exhibits enhanced anti-tumor effects in mice tests.

In May 2023, the Company obtained a license for the STAR-CRISPR™ gene editing technology. This license enables the Company to create programs for advanced gene-edited CAR-iPS NKT cell therapy to treat various types of cancer including solid tumors. The Company's project to develop BP2202 as prototype CAR-iPSNKT cells targeting BCMA for multiple myeloma is underway. In parallel, the Company is preparing the creation of the master cell bank of iPS cells from a healthy donor and GMP-compliant manufacturing for an investigational new drug application in March 2026. The Company entered into a process development and manufacturing agreement with Cellistic, a leader in advanced iPS cell therapy manufacturing, in December 2024. The robust manufacturing process with high purity and high proliferation established by the Company is to be transferred to Cellistic, having its unique iPS cells-culturing platform using 3D bioreactors.

<HER2 CAR-T cell therapy: BP2301>

BP2301 is a chimeric antigen receptor gene-transfected T-cell (CAR-T cell) therapy which targets HER2 that is highly expressed in various solid tumors. Until today, CAR-T cell therapies have been

approved globally with excellent clinical benefits demonstrated in clinical trials for hematologic cancers. However, the deployment of CAR-T cell therapies to treat solid tumors, from which a larger number of people suffer, faces a challenge due to the lack of sufficient clinical efficacy of CAR-T cells resulting from their exhaustion and dysfunction in the immune-suppressive tumor microenvironment.

The Company has successfully overcome this challenge by developing a technology using CAR-T cells rich in stem cell memory phenotypes. Owing to the high replicability and long-term viability of such CAR-T cells in the patient's body, BP2301 is a promising solution to enhance resistance to T-cell exhaustion and to achieve long-lasting anti-tumor effects in the tumor microenvironment. This success is attributed to the joint development of a novel cell culture method with Professor Yozo Nakazawa and Professor Shigeki Yagyu of Shinshu University, based on Professor Nakazawa's non-viral gene transfer method.

In the Phase 1 investigator-initiated clinical trial started in May 2022 at Shinshu University, the treatment of HER2-positive relapsed or advanced sarcomas and gynecological malignancies is being tested.

Antibody drugs

Since immune checkpoint molecules[3] or immunomodulatory molecules suppress the immune system to eliminate tumor cells, the Company is developing antibody drugs capable of binding to such molecules and inhibiting their function. The Company's antibody drug development pipelines cover BP1200, BP1202, BP1210, BP1212 and BP1223. BP1200 and BP1202 target CD73 and CD39 respectively, both of which help prevent the production of immunosuppressive adenosine. BP1210 targets TIM-3, which is expressed in immune cells and restraints anti-tumor immunity. BP1212 is a CD39/TIM-3 bispecific antibody targeting immune cells which co-express CD39 and TIM-3 and simultaneously blocking multiple immunosuppressive mechanisms. Furthermore, BP1223 is a T cell engager[4] that binds to both CD39, which is expressed on cancer cells, and CD3, which is expressed on T cells. The effort to obtain further non-clinical data for antibody profiling is underway during the course of licensing activities.

Regarding BP1223, the Company's joint research with National Cancer Center Hospital East is underway for non-clinical studies to confirm pharmaceutical benefits, pharmacological effects and mode-of-action analysis targeting blood cancer including acute myeloid leukemia. Some of the research results were presented at the 66th American Society of Hematology Annual Meeting and Exposition in December, 2024.

Cancer vaccines

<Fully-personalized neoantigen vaccine with immune checkpoint antibodies: BP1209>

BP1209 is a new platform of fully-personalized neoantigen vaccines[5] optimized to induce each individual patient's anti-tumor immunity targeting immunogenic neoantigens derived from mutations in cancer cell derived genes. BP1209 uses checkpoint inhibitor antibodies to deliver neoantigen peptides to dendritic cells acting as messengers to T-cells. To facilitate the binding of BP1209 to such antibodies, the Company's original linker technology is utilized. The Company has demonstrated in a tumor-bearing mouse model that efficient delivery of vaccine antigens to dendritic cells which direct anti-tumor immunity can induce many more cancer-killing T-cells which identify and attack neoantigens than peptides alone do.

As a consequence of all of the foregoing, the Company recorded the financial results for the nine months ended December 31, 2024 as follows : operating loss of 815,698 thousand yen (947,173 thousand yen in the corresponding period of the prior year), ordinary loss of 812,290 thousand yen (947,580 thousand yen in the corresponding period of the prior year), and net loss of 815,085 thousand yen (953,765 thousand yen in the corresponding period of the prior year).

<Glossary>

1. NKT cell

An immune cell combining the properties of natural killer (NK) cells and T-cells and serving as a functional bridge between innate and acquired immunity. NKT cells have the ability to directly kill cancer cells through T-cell receptors or NK cell receptors and at the same time have an adjuvant action that activates other immune cells such as T-cells and dendritic cells. When activated, NKT cells produce a variety of cytokines and promote the activation of NK cells belonging to the innate immune system and the maturation of dendritic cells. Mature dendritic cells further proliferate and activate killer T-cells belonging to the acquired immune system, thereby synergistically enhancing anti-tumor effects.

2. CAR-T cell therapy

Chimeric antigen receptor T-cell therapy. Chimeric antigen receptors that recognize antigens expressed by cancer cells are gene-transfected into T-cells (a type of lymphocyte with anti-tumor immunity), which are then grown in culture and administered.

3. Immune checkpoint molecule

A group of molecules that suppress the immune response to self as well as suppress excessive immune responses in order to maintain immune homeostasis. In cancer immunity, they are present to prevent the attack on self by over-activation, but in the carcinogenic process, they are used by cancer cells to evade attack from the immune system and to proliferate.

4. T cell engager

T cell engagers are antibodies engineered to redirect the immune system's T cells to recognize and kill cancer cells. They are designed to bind to a target antigen expressed on a cancer cell and to a trigger molecule on T cells.

5. Fully personalize neoantigen vaccine

A tailor-made cancer vaccine that searches for neoantigens in cancer cells of individual patients. Clinical trials currently conducted overseas by academia and leading development companies include those for mRNA vaccines, that is, lipid nanoparticles (LNP) loaded with mRNAs coding for neoantigens.

(2) Overview of Financial Position for the Nine Months Ended December 31, 2024

(i) Assets

As of December 31, 2024, total assets were 1,450,228 thousand yen, an increase of 219,971 thousand yen from the end of the prior fiscal year. The main factors for this include an increase of 203,608 thousand yen in cash and deposits due to issuance of shares and straight bonds.

(ii) Liabilities

As of December 31, 2024, total liabilities were 318,354 thousand yen, an increase of 67,084 thousand yen from the end of the prior fiscal year. The main factors for this include an increase of 50,000 thousand yen in current portion of bonds payable.

(iii) Net assets

As of December 31, 2024, net assets were 1,131,873 thousand yen, an increase of 152,886 thousand yen from the end of the prior fiscal year. The main factors for this include an increase of 968,968 thousand yen in total in capital stock and capital surplus due to issuance of new shares, and a decrease of a net loss of 815,085 thousand yen. As a result of the above, equity ratio was 76.5% compared to 77.7% at the end of the prior fiscal year.

(3) Outlook for the Fiscal Year Ending March 31, 2025

Our recent business outlook is the same as the projected financial results announced on May 10, 2024.

2. Financial Statements and Primary Notes

(1) Balance Sheets

(Thousands of yen)

	As of March 31, 2024	As of December 31, 2024
Assets		
Current assets		
Cash and deposits	1,057,360	1,260,968
Accounts receivable - trade	6	36
Other	123,594	139,925
Total current assets	1,180,960	1,400,931
Non-current assets		
Property, plant and equipment	0	0
Intangible assets	0	0
Investments and other assets	49,296	49,296
Total non-current assets	49,296	49,296
Total assets	1,230,257	1,450,228
Liabilities		
Current liabilities		
Accounts payable - trade	20	24
Current portion of bonds payable	112,500	162,500
Income taxes payable	12,815	9,940
Other	65,675	78,825
Total current liabilities	191,011	251,291
Non-current liabilities		
Provision for retirement benefits	37,610	44,345
Asset retirement obligations	22,648	22,718
Other	0	0
Total non-current liabilities	60,258	67,063
Total liabilities	251,270	318,354
Net assets		
Shareholders' equity		
Capital stock	650,661	1,135,145
Capital surplus	2,959,195	3,443,680
Retained earnings	-2,653,715	-3,468,800
Treasury stock	-0	-0
Total shareholders' equity	956,141	1,110,024
Share acquisition rights	22,845	21,849
Total net assets	978,987	1,131,873
Total liabilities and net assets	1,230,257	1,450,228

(2) Statements of Operations

(Thousands of yen)

	Nine months ended December 31, 2023	Nine months ended December 31, 2024
Net sales	67	89
Cost of sales	16	22
Gross profit	50	67
Selling, general and administrative expenses	947,223	815,765
Operating income	-947,173	-815,698
Non-operating income		
Interest income	6	61
Settlement income	—	10,569
Other	186	4
Total non-operating income	193	10,635
Non-operating expenses		
Foreign exchange losses	510	3,257
Share issuance cost	—	3,880
Other	90	90
Total non-operating expenses	601	7,228
Ordinary income	-947,580	-812,290
Extraordinary losses		
Impairment loss	4,760	1,369
Other	—	0
Total extraordinary losses	4,760	1,370
Income before income taxes	-952,340	-813,660
Income taxes - current	1,425	1,425
Total income taxes	1,425	1,425
Net income	-953,765	-815,085

(3) Notes to Financial Statements

(Segment information, etc.)

Segment information is omitted as the Company operates in the single business segment of the pharmaceutical development business and there is no other significant segment information.

(Notes on significant changes in shareholders' equity)

During the nine months ended December 31, 2024, 4,650,000 shares of common stock were issued for total issue price of 299,250 thousand yen by execution of the series 16 warrants and 12,105,000 shares of common stock were issued for total issue price of 667,095 thousand yen by execution of the series 17 warrants to increase capital stock and legal capital surplus by 484,484 thousand yen each, including 1,534 thousand yen for the series 16 warrants and 1,089 thousand yen for the series 17 warrants transferred from share acquisition rights. As of December 31, 2024, capital stock was 1,135,145 thousand yen and capital surplus was 3,443,680 thousand yen.

(Notes on going concern assumption)

Not applicable.

(Supplementary information on cash flows)

Statements of cash flows for the nine months ended December 31, 2024 are omitted due to the quarterly closing. Information of depreciation including amortization of intangible assets for the nine months ended December 31, 2024 is shown below:

(Thousands of yen)

	Nine months ended December 31, 2023	Nine months ended December 31, 2024
Depreciation	310	—

(Significant subsequent events)

(Exercise of the series 17 warrants)

During the period from January 1, 2025 to February 14, 2025, 650,000 shares of common stock have been issued for total issue price of 27,150 thousand yen by execution of the series 17 warrants to increase capital stock and legal capital surplus by 13,604 thousand yen each, including 58 thousand yen transferred from share acquisition rights.