Financial Results for the Nine Months ended December 31, 2023
[Japanese GAAP] (non-consolidated)

February 9, 2024

BrightPath Biotherapeutics Co., Ltd. Listed Market Growth, TSE
TSE Code 4594 URL https://www.brightpathbio.com/english/index.html
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Scheduled date to file quarterly securities report: : February 9, 2024
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 fiscal for the nine months ended December 31, 2023 (April 1, 2023 – December 31, 2023)

(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, 2023	0	-98.7	-947	—	-947	—	-953	—
December 31, 2022	5	—	-1,218	—	-1,223	—	-1,225	—

	Net income per share	Fully diluted net income per share
Nine months ended	Yen	Yen
December 31, 2023	-15.14	—
December 31, 2022	-20.91	—

(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, 2023	1,428	772	52.4
March 31, 2023	1,701	1,567	90.9

(Reference) Shareholders' equity As of December 31, 2023 747 million yen
As of March 31, 2023 1,547 million yen

2. Dividends

	Annual dividends per share				
	1Q	2Q	3Q	4Q	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended March 31, 2023	—	0.00	—	0.00	0.00
Fiscal year ending March 31, 2024	—	0.00	—		
Fiscal year ending March 31, 2024 (Forecast)				0.00	0.00

(Note) Revisions to the forecast of cash dividends most recently announced: None

3. Projected financial results for the fiscal year ending March 31, 2024 (April 1, 2023 – March 31, 2024)

(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	-98.7	-1,588	—	-1,589	—	-1,592	—	-24.04

(Note) Revisions to the projected financial results most recently announced: Yes

[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, 2023	64,841,300 shares	As of March 31, 2023	62,891,200 shares
2) Number of shares of treasury stock at the end of the period	As of December 31, 2023	1 share	As of March 31, 2023	1 share
3) Average number of shares during the period	9 months ended December 31, 2023	63,008,301 shares	9 months ended December 31, 2022	58,603,295 shares

* These financial results are outside the scope of audits by a certified public accountant or an audit corporation.
* 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. Qualitative Information of Business Results for the Nine Months Ended December 31, 2023, (3) Outlook for the Fiscal Year Ending March 31, 2024” on page 5 of the attachment.

Contents of the Attachment

1. Qualitative Information of Business Results for the Nine Months Ended December 31, 2023

(1) Overview of Operating Results

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, 2023.

Cell therapy agents

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

BP2201(iPS-NKT) is a novel allogeneic cell therapy candidate for cancer treatment that uses natural killer T-cells (NKT cells)[1] with manifold anti-tumor effects including killing cancer cells, manufactured at high yield by iPS cell technologies. Cancer treatment has entered a new age with the appearance of CAR-T cell[2] drug that is a combination of T-cells collected either from patients themselves or from healthy individuals and chimeric antigen receptors (CAR) that can recognize cancer antigens to enhance its ability killing cancer cells. For hematologic cancer treatments, several CAR-T cell products that are genetically modified based on T-cells collected from patients themselves have already been approved and followed by development of next-generation CAR-T cells with high function. The Company is developing a differentiated CAR-T cell product (CAR-iPSNKT) by adopting NKT cells generated from healthy donor-derived iPS cells as its T-cell.

The Company, so far, obtained exclusive license to use a patent in Japan, the US, and the EU to protect the Company’s extensive and exclusive use of iPS-derived NKT cells for allogeneic cell therapy from Institute of Physical and Chemical Research (a.k.a. RIKEN), developed a manufacturing process to differentiate iPS cells in the master iPS cell bank into high-purity and high-yield NKT cells and implemented a gene-editing technology. As for clinical application of iPS-NKT, an investigator-initiated Phase 1 trial of iPS-NKT in patients with head and neck cancers (started in June 2020) is underway at Chiba University. This Phase 1 trial stays on trach and, un until now, no safety issues have been reported.

This platform serves as a cornerstone for developing novel iPS-NKT cells by transducing CAR T-cells targeting various tumor antigens and ensures the application of iPS-NKT cells to treatment of various types of cancer in many regions of the world.

<HER2 CAR-T cell therapy: BP2301>

BP2301 is a chimeric antigen receptor gene-transfected T-cell (CAR-T cell) therapy that targets HER2 that is highly expressed in various solid tumors. In the Phase I 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.

Until today, CAR-T cell therapies targeting hematologic cancers have been approved globally with excellent clinical benefits demonstrated in clinical trials. 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. To overcome this challenge, BP2301 contains a large number of stem cell-like immune memory phenotype cells that are characterized by excellent replication and long-term viability in the body and are expected to provide exhaustion resistance and sustained anti-tumor effects in the tumor microenvironment. It has been allowed through 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.

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 and BP1212. 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. Furthermore, BP1212 is a CD39/TIM-3 bispecific antibody targeting immune cells which co-express CD39 and TIM-3 and simultaneously blocking multiple immunosuppressive mechanisms.

Since the Company had ascertained high CD39 expression in regulatory T-cells (Tregs), which strongly suppress tumor immunity for specific cancer types and tumor tissues, the Company has altered BP1202 to add the function to selectively eliminate tumor cells and Tregs. In addition, the target combination of BP1212 is a potential candidate for the first-in-class drug, that is, the first breakthrough drug approved in the same drug class.

Proof of concept has been achieved in the pre-clinical phase for these novel antibody drugs.

Cancer vaccines

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

BP1209 is a new platform of fully personalized neoantigen vaccines[4] 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.

<Cancer peptide vaccine: GRN-1201>

GRN-1201 is a cancer peptide vaccine consisting of four tumor associated antigen-derived HLA[5]-A2 restricted peptides. HLA-A2 types are common among Europeans and Americans, and GRN-1201 is intended for global deployment including the US and Europe. In May 2022, the Company decided on the early termination of the Phase II clinical trial of the cancer peptide vaccine GRN-1201 in combination with the immune checkpoint inhibitory antibody targeting PD-1 for non-small cell lung cancer conducted in the US. At present, the Company is seeking a development partner to initiate a new clinical trial.

As a consequence of all of the foregoing, the Company recorded the financial results for the nine months ended December 31, 2023 as follows: operating loss of 947,173 thousand yen (1,218,371 thousand yen in the corresponding period of the prior year), ordinary loss of 947,580 thousand yen (1,223,957 thousand yen in the corresponding period of the prior year), and net loss of 953,765 thousand yen (1,225,382 thousand yen in the corresponding period of the prior year).

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.

<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, they 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
Chimeric antigen receptor gene-modified T-cell. Chimeric antigen receptors are gene-transfected into T-cells (a type of lymphocyte with anti-tumor immunity) to recognize antigens expressed by cancer cells.

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. 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.

5. HLA
Human leukocyte antigens are proteins which are expressed on the surface of almost all cells in the human body and regulate the immune system. The HLA system, which is also known as the major histocompatibility complex (MHC), is involved in the elimination of pathogens such as bacteria and viruses, cancer cell rejection and organ transplant rejection. HLA expression occurs on the surface of cancer cells as well. In the mechanism of action of cancer vaccines, HLAs bind to peptides formed from antigenic peptides in cancer cells, migrate to the cancer cell surface, and enable cytotoxic T-cells (CTL) to recognize cancer cells. HLA are markers to distinguish self and non-self, and there are diverse types of HLAs to differentiate many varieties of non-self from self. Peptides bind to a specific type of HLA alone and do not bind to any other different types.

(2) Overview of Financial Position

(i) Assets

As of December 31, 2023, total assets were 1,428,572 thousand yen, a decrease of 272,872 thousand yen from the end of the prior fiscal year. The main factors for this include a decrease of 234,026 thousand yen due to expenditures related to research and development, etc. in cash and deposits.

(ii) Liabilities

As of December 31, 2023, total liabilities were 655,819 thousand yen, an increase of 521,915 thousand yen from the end of the prior fiscal year. The main factors for this include a record of 500,000 thousand yen in current portion of bonds payable by issuing the series 2 unsecured bonds.

(iii) Net assets

As of December 31, 2023, net assets were 772,753 thousand yen, a decrease of 794,787 thousand yen from the end of the prior fiscal year. The factor for this is a net loss of 953,765 thousand yen.

As a result of the above, equity ratio was 52.4% compared to 90.9% at the end of the prior fiscal year.

(3) Outlook for the Fiscal Year Ending March 31, 2024

We revised our projected financial results for the fiscal year ending March 31, 2024 from those announced on May 12, 2023. In accordance with “Announcement of Issuance of Series 16 Moving Strike Warrants and Unsecured Bonds (Private Placement Bonds:PPB) dated November 14, 2023, we propelled our development and research activities including development of CAR-iNKT prototype product.

3. Financial Statements and Primary Notes

(1) Balance Sheets

(Thousands of yen)

	As of March 31, 2023	As of December 31, 2023
Assets		
Current assets		
Cash and deposits	1,530,969	1,296,943
Accounts receivable - trade	55	24
Other	120,184	82,307
Total current assets	1,651,210	1,379,275
Non-current assets		
Property, plant and equipment	0	0
Intangible assets	0	0
Investments and other assets	50,234	49,296
Total non-current assets	50,234	49,296
Total assets	1,701,444	1,428,572
Liabilities		
Current liabilities		
Accounts payable - trade	77	18
Current portion of bonds payable	—	500,000
Income taxes payable	10,409	5,976
Other	66,072	91,907
Total current liabilities	76,558	597,902
Non-current liabilities		
Provision for retirement benefits	34,789	35,291
Asset retirement obligations	22,556	22,625
Other	0	0
Total non-current liabilities	57,345	57,916
Total liabilities	133,903	655,819
Net assets		
Shareholders' equity		
Capital stock	362,185	439,412
Capital surplus	2,670,720	2,747,947
Retained earnings	-1,485,633	-2,439,399
Treasury stock	-0	-0
Total shareholders' equity	1,547,272	747,960
Share acquisition rights	20,268	24,792
Total net assets	1,567,541	772,753
Total liabilities and net assets	1,701,444	1,428,572

(2) Statements of Operations

(Thousands of yen)

	Nine months ended December 31, 2022	Nine months ended December 31, 2023
Net sales	5,229	67
Cost of sales	1,282	16
Gross profit	3,946	50
Selling, general and administrative expenses	1,222,318	947,223
Operating income	-1,218,371	-947,173
Non-operating income		
Interest income	11	6
Other	546	186
Total non-operating income	557	193
Non-operating expenses		
Foreign exchange losses	4,018	510
Share issuance cost	2,064	—
Other	61	90
Total non-operating expenses	6,144	601
Ordinary income	-1,223,957	-947,580
Extraordinary losses		
Impairment loss	—	4,760
Total extraordinary losses	—	4,760
Income before income taxes	-1,223,957	-952,340
Income taxes - current	1,425	1,425
Total income taxes	1,425	1,425
Net income	-1,225,382	-953,765

(3) Notes to Financial Statements

(Notes on going concern assumption)

Not applicable.

(Notes on significant changes in shareholders' equity)

Capital stock and capital surplus increased by 77,226 thousand yen each by execution of the series 16 warrants during the nine months ended December 31, 2023. As of December 31, 2023, capital stock was 439,412 thousand yen and capital surplus was 2,747,947 thousand yen.

(Significant subsequent events)

(Exercise of Series 16 warrants)

The series 16 warrants with exercise price amendment clause (third-party allotment) held by Macquarie Bank Limited has been partially exercised during the period from January 1, 2024 to February 8, 2024. Summary of the exercise of the warrants is as follows:

1. Class and number of shares issued Common stock 2,050,000 shares
2. Total amount of issue price 160,350 thousand yen

As a result, capital stock and capital surplus increased by 80,513 thousand yen each, including 676 thousand yen transferred from share acquisition rights.