Financial Results for the Six Months ended September 30, 2023 [Japanese GAAP] (non-consolidated)

November 10, 2023

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: : November 10, 2023
Scheduled date of dividend payment commencement : —
Supplementary materials for financial statements : None
Briefing of financial results : Yes (for analysts/institutional investors)

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

1. Financial results for the six months ended September 30, 2023 (April 1, 2023 – September 30, 2023)

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

	Net sales		Operating income		Ordinary income		Net income	
Six months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
September 30, 2023	0	-75.0	-550	—	-551	—	-553	—
September 30, 2022	0	-31.9	-805	—	-809	—	-810	—

	Net income per share	Fully diluted net income per share
Six months ended	Yen	Yen
September 30, 2023	-8.81	—
September 30, 2022	-14.20	—

(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	%
September 30, 2023	1,163	1,013	85.4
March 31, 2023	1,701	1,567	90.9

(Reference) Shareholders' equity As of September 30, 2023 993 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

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 prior 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	-100.0	-1,353	—	-1,353	—	-1,357	—	-21.58

(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 September 30, 2023	62,891,200 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 September 30, 2023	1 share	As of March 31, 2023	1 share
3) Average number of shares during the period	6 months ended September 30, 2023	62,891,199 shares	6 months ended September 30, 2022	57,094,711 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 Six Months Ended September 30, 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 Six Months Ended September 30, 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 six months ended September 30, 2023.

Cell therapy agents

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

BP2201 (iPS-NKT) is a novel allogeneic cell therapy agent for cancer treatment that uses natural killer T-cells (NKT cells)[1] induced from iPS cells. This cell therapy agent is a kind of T-cell engineered with chimeric antigen receptors (CAR) that can recognize cancer antigens, and such CAR-T cell therapy[2] is currently under development globally. Compared with T-cells, NK cells or γδT cells typically used in other companies' development projects, NKT cells have a differentiated function and are expected to show a greater presence as immune cells which will underpin the future CAR-T cell therapy.

The Company has been promoting the research and development of the cellular therapy using NKT cells, jointly with Institute of Physical and Chemical Research (a.k.a. RIKEN). In November 2022, the Company exercised the option right to obtain a worldwide exclusive license to develop, manufacture and market BP2201 from RIKEN.

This license has allowed the Company to build an iPS-NKT platform that consists of: (1) the patent in Japan, the US, and the EU to protect the Company's extensive and exclusive use of iPSC-derived NKT cells for allogeneic cell therapy, (2) the master iPS cell bank (MCB), and (3) the manufacturing process capable of differentiating iPS cells in the MCB into high-purity and high-yield NKT cells. The clinical safety and efficacy of the MCB is expected to be demonstrated in the ongoing clinical trial.

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.

At the Annual Meeting of Society for Immunotherapy of Cancer held in the US in November 2022 (SITC 2022), the Company reported the non-clinical data of the world's first prototype CAR iPS-NKT created on the iPS-NKT platform, demonstrating anti-tumor effects in vitro[3].

The company entered into research and licensing agreement in May 2023 to receive non-exclusive rights to Artisan's STAR-CRISPR™ editing platform to accelerate development of iPS-NKT cells.

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 track and, up until now, no safety issues have been reported.

<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[4] 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, the Company has altered BP1202 to add the function of selectively eliminate Tregs. Due to the combination of CD39 and TIM-3 as targets, BP1212 is a potential candidate for the first-in-class drug, that is, the first breakthrough drug approved in the same drug class. The pre-clinical data for BP1212 were reported in SITC 2022 in November 2022. 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[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.

<Cancer peptide vaccine: GRN-1201>

GRN-1201 is a cancer peptide vaccine consisting of four tumor associated antigen-derived HLA[6]-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 six months ended September 30, 2023 as follows: operating loss of 550,569 thousand yen (805,068 thousand yen in the corresponding period of the prior year), ordinary loss of 551,566 thousand yen (809,792 thousand yen in the corresponding period of the prior year), and net loss of 553,922 thousand yen (810,742 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 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. in vitro

Experiments in a model environment, often in a laboratory tube.

4. 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.

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.

6. 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 September 30, 2023, total assets were 1,163,667 thousand yen, a decrease of 537,777 thousand yen from the end of the prior fiscal year. The main factors for this include a decrease of 467,781 thousand yen due to expenditures related to research and development, etc. in cash and deposits.

(ii) Liabilities

As of September 30, 2023, total liabilities were 150,048 thousand yen, an increase of 16,145 thousand yen from the end of the prior fiscal year. The main factors for this include an increase of 13,960 thousand yen in accounts payable included in other current liabilities.

(iii) Net assets

As of September 30, 2023, net assets were 1,013,618 thousand yen, a decrease of 553,922 thousand yen from the end of the prior fiscal year. The factor for this is a decrease of a net loss of

553,922 thousand yen. As a result of the above, equity ratio was 85.4% compared to 90.9% at the end of the prior fiscal year.

(iv) Overview of Cash Flows

As of September 30, 2023, cash and cash equivalents (hereinafter “net cash”) amounted to 1,063,188 thousand yen, a decrease of 467,781 thousand yen from the end of the prior fiscal year. The situation of each cash flow for the six months ended September 30, 2023 and the underlying factors are as follows:

(Cash flows from operating activities)

Net cash used in operating activities amounted to 466,327 thousand yen (588,604 thousand yen used in the corresponding period of the prior year). This was mainly due to recording loss before income taxes of 552,972 thousand yen.

(Cash flows from investing activities)

Net cash used in investing activities amounted to 1,454 thousand yen (none used in the corresponding period of the prior year). This was due to purchase of intangible assets.

(Cash flows from financing activities)

No cash flows were recorded in financing activities (197,491 thousand yen provided in the corresponding period of the prior year).

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

Our recent business outlook is the same as the projected financial results announced on May 12, 2023.

2. Financial Statements and Primary Notes

(1) Balance Sheets

(Thousands of yen)

	As of March 31, 2023	As of September 30, 2023
Assets		
Current assets		
Cash and deposits	1,530,969	1,063,188
Accounts receivable - trade	55	30
Other	120,184	50,214
Total current assets	1,651,210	1,113,432
Non-current assets		
Property, plant and equipment	0	0
Intangible assets	0	0
Investments and other assets	50,234	50,234
Total non-current assets	50,234	50,234
Total assets	1,701,444	1,163,667
Liabilities		
Current liabilities		
Accounts payable - trade	77	12
Income taxes payable	10,409	8,836
Other	66,072	83,148
Total current liabilities	76,558	91,997
Non-current liabilities		
Provision for retirement benefits	34,789	35,449
Asset retirement obligations	22,556	22,602
Other	0	0
Total non-current liabilities	57,345	58,051
Total liabilities	133,903	150,048
Net assets		
Shareholders' equity		
Capital stock	362,185	362,185
Capital surplus	2,670,720	2,670,720
Retained earnings	-1,485,633	-2,039,555
Treasury stock	-0	-0
Total shareholders' equity	1,547,272	993,350
Share acquisition rights	20,268	20,268
Total net assets	1,567,541	1,013,618
Total liabilities and net assets	1,701,444	1,163,667

(2) Statements of Operations

(Thousands of yen)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Net sales	179	44
Cost of sales	44	11
Gross profit	134	33
Selling, general and administrative expenses	805,202	550,603
Operating income	-805,068	-550,569
Non-operating income		
Interest income	11	6
Other	546	186
Total non-operating income	557	193
Non-operating expenses		
Foreign exchange losses	4,146	1,190
Share issuance cost	1,073	—
Other	61	—
Total non-operating expenses	5,281	1,190
Ordinary income	-809,792	-551,566
Extraordinary losses		
Impairment loss	—	1,406
Total extraordinary losses	—	1,406
Income before income taxes	-809,792	-552,972
Income taxes - current	950	950
Total income taxes	950	950
Net income	-810,742	-553,922

(4) Statements of Cash Flows

(Thousands of yen)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Cash flows from operating activities		
Loss before income taxes	-809,792	-552,972
Depreciation	8,359	48
Impairment loss	—	1,406
Interest and dividend income	-11	-6
Decrease (increase) in notes and accounts receivable - trade	16,506	24
Increase (decrease) in notes and accounts payable - trade	-63	-64
Increase (decrease) in retirement benefit liability	805	660
Other, net	198,200	86,468
Subtotal	-585,604	-464,436
Interest and dividend income received	13	9
Interest paid	-202	—
Income taxes paid	-2,420	-1,900
Net cash provided by (used in) operating activities	-588,604	-466,327
Cash flows from investing activities		
Purchase of intangible assets	—	-1,454
Net cash provided by (used in) investing activities	—	-1,454
Cash flows from financing activities		
Redemption of bonds	-87,500	—
Purchase of treasury stock	-0	—
Proceeds from issuance of shares resulting from exercise of share acquisition rights	284,991	—
Net cash provided by (used in) financing activities	197,491	—
Net increase (decrease) in cash and cash equivalents	-391,113	-467,781
Cash and cash equivalents at beginning of period	2,305,026	1,530,969
Cash and cash equivalents at end of period	1,913,913	1,063,188

(3) Notes to Financial Statements

(Notes on going concern assumption)

Not applicable.

(Notes on significant changes in shareholders' equity)

Not applicable.