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

August 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: : August 10, 2023
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 three months ended June 30, 2023 (April 1, 2023 – June 30, 2023)

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

	Net sales		Operating income		Ordinary income		Net income	
Three months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
June 30, 2023	0	-84.2	-293	—	-293	—	-295	—
June 30, 2022	0	-50.0	-545	—	-548	—	-548	—

	Net income per share	Fully diluted net income per share
Three months ended	Yen	Yen
June 30, 2023	-4.70	—
June 30, 2022	-9.75	—

(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	%
June 30, 2023	1,387	1,271	90.2
March 31, 2023	1,701	1,567	90.9

(Reference) Shareholders' equity As of June 30, 2023 1,251 million yen
As of March 31, 2022 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	—				
Fiscal year ending March 31, 2024 (Forecast)		0.00	—	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 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	-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 June 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 June 30, 2023	1 share	As of March 31, 2023	1 share
3) Average number of shares during the period	3 months ended June 30, 2023	62,891,199 shares	3 months ended June 30, 2022	56,266,396 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 Three Months Ended June 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 Three Months Ended June 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 three months ended June 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. The Company is going to expedite pre-clinical testing for these novel antibody drugs and aiming to achieve pre-clinical proof of concept for all of them.

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 reviewing the original trial subject and protocol and finding a way to commence a new clinical trial with the development partner.

As a consequence of all of the foregoing, the Company recorded the financial results for the three months ended June 30, 2023 as follows : operating loss of 293,435 thousand yen (545,423 thousand yen in the corresponding period of the prior year), ordinary loss of 293,875 thousand yen (548,221 thousand yen in the corresponding period of the prior year), and net loss of 295,756 thousand yen (548,696 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 June 30, 2023, total assets were 1,387,441 thousand yen, a decrease of 314,003 thousand yen from the end of the prior fiscal year. The main factors for this include a decrease of 266,977 thousand yen due to expenditures related to research and development, etc. in cash and deposits.

(ii) Liabilities

As of June 30, 2023, total liabilities were 115,656 thousand yen, a decrease of 18,247 thousand yen from the end of the prior fiscal year. The main factors for this include a decrease of 13,636 thousand yen in accounts payable included in other current liabilities.

(iii) Net assets

As of June 30, 2023, net assets were 1,271,784 thousand yen, a decrease of 295,756 thousand yen from the end of the prior fiscal year. The factor for this is a decrease of a net loss of 295,756 thousand

yen. As a result of the above, equity ratio was 90.2% compared to 90.9% at the end of the prior fiscal 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.

3. Financial Statements and Primary Notes

(1) Balance Sheets

(Thousands of yen)

	As of March 31, 2023	As of June 30, 2023
Assets		
Current assets		
Cash and deposits	1,530,969	1,263,992
Accounts receivable - trade	55	18
Other	120,184	73,195
Total current assets	1,651,210	1,337,206
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	1,387,441
Liabilities		
Current liabilities		
Accounts payable - trade	77	4
Income taxes payable	10,409	4,418
Other	66,072	53,011
Total current liabilities	76,558	57,434
Non-current liabilities		
Provision for retirement benefits	34,789	35,642
Asset retirement obligations	22,556	22,579
Other	0	0
Total non-current liabilities	57,345	58,221
Total liabilities	133,903	115,656
Net assets		
Shareholders' equity		
Capital stock	362,185	362,185
Capital surplus	2,670,720	2,670,720
Retained earnings	-1,485,633	-1,781,389
Treasury stock	-0	-0
Total shareholders' equity	1,547,272	1,251,516
Share acquisition rights	20,268	20,268
Total net assets	1,567,541	1,271,784
Total liabilities and net assets	1,701,444	1,387,441

(2) Statements of Operations

(Thousands of yen)

	Three months ended June 30, 2022	Three months ended June 30, 2023
Net sales	106	16
Cost of sales	26	4
Gross profit	79	12
Selling, general and administrative expenses	545,503	293,447
Operating income	-545,423	-293,435
Non-operating income		
Other	308	186
Total non-operating income	308	186
Non-operating expenses		
Foreign exchange losses	2,428	626
Share issuance cost	617	—
Other	61	—
Total non-operating expenses	3,106	626
Ordinary income	-548,221	-293,875
Extraordinary losses		
Impairment loss	—	1,406
Total extraordinary losses	—	1,406
Income before income taxes	-548,221	-295,281
Income taxes - current	475	475
Total income taxes	475	475
Net income	-548,696	-295,756

(3) Notes to Financial Statements

(Notes on going concern assumption)

Not applicable.

(Notes on significant changes in shareholders' equity)

Not applicable.